IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

LAUREN SOUTER INDIVIDUALLY, AND ON BEHALF OF OTHERS SIMILARLY SITUATED, Plaintiff-Appellant,

v.

EDGEWELL PERSONAL CARE COMPANY, EDGEWELL PERSONAL CARE BRANDS, LLC, and EDGEWELL PERSONAL CARE, LLC, Defendants-Appellees

> On Appeal from the United States District Court For the Southern District of California No. 3:20-cv-01486 Hon. Todd W. Robinson

APPELLEES' SUPPLEMENTAL EXCERPTS OF RECORD Volume 1 of 1

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7	putative Classes							
8								
9	IN THE UNITED STA	ATES DISTRICT COURT						
	FOR THE SOUTHERN I	DISTRICT OF CALIFORNIA						
10	LAUREN SOUTER, individually,	CASE NO. '20CV1486 CAB BLM						
11	and on behalf of others similarly							
12	situated,	CLASS ACTION COMPLAINT FOR:						
13	Plaintiff,	1. UNFAIR AND UNLAWFUL						
14	vs.	BUSINESS ACTS AND PRACTICES						
15		(CAL. BUS & PROF. CODE §17200 ET						
16	EDCEWELL DEDCOMAL CADE	SEQ.); 2. DECEPTIVE ADVERTISING						
	EDGEWELL PERSONAL CARE COMPANY, EDGEWELL	PRACTICES (CAL. BUS & PROF.						
17	COMPANY, EDGEWELL PERSONAL CARE BRANDS LLC, and EDGEWELL PERSONAL	CODE §§ 17500, ET SEQ.);						
18	CARE, LLC,	3. CONSUMER LEGAL REMEDIES						
19	Defendants.	ACT (CAL. CIV. CODE § 1750, ET SEQ.);						
20		4. BREACH OF EXPRESS						
21		WARRANTY; AND						
22		5. QUASI-CONTRACT.						
23		DEMAND FOR JURY TRIAL						
24								
25	Plaintiff Lauren Souter on behalf a	of herself and others similarly situated, by and						
26		by files this Class Action Complaint against						
27	Defendants Edgewell Personal Care Con	npany, Edgewell Personal Care Brands, LLC,						

CLASS ACTION COMPLAINT

and Edgewell Personal Care, LLC (collectively "Defendants") and states as follows:

NATURE OF THE ACTION

- 1. This is a case about holding the manufacturers of Wet Ones hand wipes¹ responsible for truthfully and accurately labeling their Products, which are used and relied on by consumers to keep themselves and their families safe from germs.
- 2. Specifically, Plaintiff alleges that Defendants' label representations concerning the efficacy and skin safety of the Products are false and misleading, including Defendants' representations that the Products "Kill[] 99.99% of Germs" and that they are hypoallergenic and gentle on skin. Plaintiff also asserts that Defendants omit critical information concerning the limitations of the Products to "kill germs."
- 3. "Germs" is a commonly understood term as an organism that causes disease.
- 4. Contrary to Defendants' material representations, however, the Products do not "kill" 99.99% of the organisms that cause disease.
- 5. As described in detail herein, the active ingredient in the Products, benzalkonium chloride ("BAC"), is ineffective against non-enveloped viruses, certain gram negative bacteria, and spores. In addition, the concentration of BAC in the Products and manner of application render the Products ineffective to "kill" certain "germs."
- 6. In the absence of truthful disclosures concerning the Products, consumers are falsely led to believe that they are effective—as Defendants' prominently represent—against "99.99% of Germs." If the Products were accurately labeled, however, consumers would know when they are ineffective and when they should seek alternative hand cleansing methods.

¹ Wet Ones wipes are sold in a variety of sizes, scents and variations, including Wet Ones canisters, travel packs, singles and big ones (collectively, the "Products"). This action includes in the definition of Products all sizes, scents and variations of the Products that bear the "Kills 99.99% of Germs" representation.

- 7. Defendants' skin safety representations, including that the Products are "[h]ypoallergenic" and "tough on dirt and germs, yet gentle on skin" are also false and misleading because the Products contain numerous known irritants, allergens and toxins.
- 8. BAC, for example, is an established skin irritant and has been found to cause allergic contact dermatitis.
- 9. In addition, the third most prevalent inactive ingredient in the Products, phenoxyethanol, is a recognized allergen and toxin. The United States Food and Drug Administration ("FDA") has stated that phenoxyethanol can depress the central nervous system in infants. A French medical agency cautioned consumers not to use wipes containing phenoxyethanol on children under the age of three because of concerns related to reproductive and developmental toxicity. The Product directions, however, include use instructions for children 2 years and older.
- 10. Plaintiff purchased the Products under the reasonable belief that they were accurately represented, including that the label representations were truthful. Plaintiff suffered damage, as described herein.
- 11. Plaintiff brings this action individually and on behalf of those similarly situated and seeks to represent a Nationwide Class and California Subclass (defined *infra*.). Plaintiff seeks damages, interest thereon, reasonable attorneys' fees and costs, restitution, equitable relief, and disgorgement of all benefits Defendants have enjoyed from their unlawful and/or deceptive business practices, as detailed herein. In addition, Plaintiff seeks injunctive relief to stop Defendants' unlawful conduct in the labeling and marketing of the Products. Plaintiff makes these allegations based on her personal knowledge as to herself and her own acts and observations and, otherwise, on information and belief based on investigation of counsel.

JURISDICTION AND VENUE

12. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed classes; (2) members of the proposed classes have a different citizenship from

Defendants; and (3) the claims of the proposed class members exceed \$5,000,000 in the aggregate.

- 13. This Court has personal jurisdiction over Defendants because Defendants' contacts with the forum are continuous and substantial, and Defendants intentionally availed themselves of the markets within California through their sale and distribution of the Products to California consumers and through the privilege of conducting business in California.
- 14. Venue is proper in this District pursuant to 28 U.S.C. §1391(b) because Defendants engage in continuous and systematic business activities within the State of California. Moreover, a substantial part of the events and omissions giving rise to the claims alleged herein occurred in this District. *See also* Declaration of Lauren Souter Regarding Venue Pursuant to Cal. Civ. Code § 1780(d), attached hereto as Exhibit A.

PARTIES

- 15. Plaintiff Lauren Souter is a resident of San Diego, California, who purchased the Products during the class period, as described herein. Plaintiff's claim is typical of all Class members in this regard. In addition, the advertising and labeling on the package of the Products purchased by Plaintiff, including the Products' label representations, is typical of the advertising, labeling and representation of the Products purchased by members of the Classes.
- 16. Defendant Edgewell Personal Care Company is a Missouri corporation with its principal place of business in Shelton, CT. Defendant and its agents manufacture, market, distribute, label, promote, advertise and sell the Products. At all times material hereto Defendant was conducting business in the United States, including in California, through its services as a manufacturer and supplier to various stores in California and by, among other things, maintaining agents for the customary transaction of business in California.
- 17. Defendant Edgewell Personal Care Brands, LLC is a Delaware Limited Liability Company with its principal place of business in Shelton, CT. Defendant and

its agents manufacture, market, distribute, label, promote, advertise and sell the Products. At all times material hereto Defendant was conducting business in the United States, including in California, through its services as a manufacturer and supplier to various stores in California and by, among other things, maintaining agents for the customary transaction of business in California.

- 18. Defendant Edgewell Personal Care, LLC is a Delaware Limited Liability Company with its principal place of business in Shelton, CT. Defendant and its agents manufacture, market, distribute, label, promote, advertise and sell the Products. At all times material hereto Defendant was conducting business in the United States, including in California, through its services as a manufacturer and supplier to various stores in California and by, among other things, maintaining agents for the customary transaction of business in California.
- 19. Defendants and their agents promoted, marketed and sold the Products at issue in this jurisdiction and in this judicial district. The unfair, unlawful, deceptive, and misleading advertising and labeling of the Products was prepared and/or approved by Defendants and their agents, and was disseminated by Defendants and their agents through labeling and advertising containing the misrepresentations and omissions alleged herein.

FACTUAL ALLEGATIONS

A. <u>Defendants Falsely Label and Advertise the Products as Killing 99.99% of Germs</u>

- 20. Defendants manufacture, label, market, promote, advertise, and sell the Products.
- 21. The following images depict the front and back panel representations on the Products:





- 22. Defendants make numerous false and misleading representations about the ability of the Products to kill germs and clean hands.
- 23. Defendants prominently state on the primary display panel that the Products "Kill[] 99.99% of Germs". On the back panel, Defendants state that "Wet Ones® **Antibacterial** Hand Wipes kill 99.99% of germs and wipe away dirt, providing a better clean than hand sanitizers. They are specially formulated to be tough on dirt and germs, yet gentle on skin, so you can confidently keep your hands fresh and clean when soap and water are not available." (Collectively, the "Efficacy Representations").
- 24. Under "Directions" Defendants state that "adults and children 2 years and over" should "apply to hands" and "allow skin to dry without wiping".
- 25. Defendants' Efficacy Representations are false, deceptive and materially misleading.
- 26. Germs" is defined by Merriam-Webster as, among other things, "especially: a microorganism causing disease".
- 27. The active ingredient in the Products, BAC, does not "kill" certain microorganisms causing disease, which comprise more than .01% of "germs."
- 28. In addition, the concentration and formulation of the active ingredient—.13% BAC on a hand wipe—does not "Kill[] 99.99% of Germs".

- 29. The directions render the Products additionally ineffective as they state "apply to hands" and "allow skin to dry without wiping." BAC, however, is slow to act, meaning that it generally must remain on hands for more time than soap and water or an alcohol-based hand sanitizer to "kill germs." The directions, however, do not ensure that the active ingredient remains on the hands for a sufficient amount of time to denature certain microbes.
- 30. Furthermore, the directions do not account for the condition of the hands to which the wipes are applied, which could be dirty, greasy or grimy and prevent adequate application or saturation of the product.
- 31. BAC belongs to a group of chemicals called quaternary ammonium compounds ("QAC").
- 32. BAC generally works by denaturing the proteins in a cell, including by absorbing or disrupting the cytoplasmic membrane, which causes vital substances to leak out of the cell. By this mechanism, the cell structure can be compromised, resulting in damage, disruption of essential cell processes and/or cell death. Accordingly, the outer structure of the microbe to which BAC is applied is critically important to whether BAC will be effective to denature or destroy that microbe.
- 33. According to a table published by the Center for Food Security & Public Health regarding the antimicrobial activity of certain disinfectant chemical classes, QAC disinfectants (which includes BAC) demonstrate no activity against: (i) pseudomonads (a type of gram-negative bacteria that are difficult to remove from food preparation surfaces); (ii) chlamydiae (gram-negative bacteria causing infection); (iii) non-enveloped viruses (viruses that lack a lipid bilayer); (iv) parvoviruses (DNA viruses, some of which cause infection in humans, such as "fifth disease"); (v) acid-fast bacteria (a group of bacteria classified by the ability to resist decolorization by acids for staining procedures; for example, M. tuberculosis), (vi) bacterial spores (a dormant form of bacteria; for example, C. difficile, described below), (vii) coccidia (causing infection in dogs), and (viii) prions (proteins with the ability to transmit their misfolded

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25 27 28 shape onto other proteins and which are responsible for several fatal neurodegenerative diseases in humans):

st	val of organic material always precede the use disinfectant.	Acids hydrochloric acid, scellc acid,	Alcohols ethanol	Aldehydes formaldehyde, pariformaldehyde,	Alkalis socium hydroxide, ammonium	Biguanides chlorhexidine, Nolvasan*, Chlorhex*	Halog	pens	Peroxygens accelerated hydrogen percede Rescue I, potassum peroxymonosurate (Wrkon-ST), peroxyacetic	Phenolic Compounds (Lysel Osyl Amely) Tekirol	Quaternary Ammonium Compounds (Rocal , Zephanin DiQuat , Payonol
051	susceptible		iopropanol	glutern de hytle	hydroxide, sodium carbonabi	Wromm*	hypochlant	e lodne	acid (Oxy-Sept 333)	Pheno-Tek II)	D-156
ı	mycoplasmas			-	-	-		1	122	TEC.	
	gram-positive bacteria	-		(III)	D	00		2		123	000
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	pseudomonads	2		122		B			2	000	-
	rickettslae	9		13	0	- 8				-	8
	enveloped viruses	2	0	133	- 8	2	- 5		2	Ε.	2
	chlamydiae	8	8			2		2	2	2	-
	non-enveloped viruses	- 6	8		9		-	B	2	8	-
to chemical disinfectants	fungal spores	8	2		2	2		-	E		2
	picornaviruses (Le. FMD)	8	N			N	N	N			N
	parvoviruses	N	N		[2]	N		N		[2]	- 6
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- Specifically, the structure of non-enveloped viruses, certain gram negative 34. bacteria, and spores render BAC substantially ineffective because BAC cannot readily permeate or disturb the cell membrane and process.
- Non-enveloped viruses. The Products are substantially ineffective at 35. "killing" non-enveloped viruses, including (i) norovirus, (ii) poliovirus, (iii) polyomavirus, (iv) human papillomavirus, and (v) picornavirus.
- There are numerous strains or types of each of these groups of non-36. enveloped viruses, which are responsible for tens of millions of cases of infection in the United States each year.
- For example, there are approximately 25 different strains of norovirus that affect humans. According to the CDC, each year on average in the United States, norovirus causes 19 to 21 million cases of vomiting and diarrhea illness, including

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2,270,000 outpatient clinic visits (mostly in young children), 465,000 emergency room visits (mostly in young children), 109,000 hospitalizations, and 900 deaths (mostly in adults 65 and older).

- 38. According to the CDC, hand washing with soap and water is more effective than hand sanitizing at removing certain kinds of germs, including norovirus. In fact, the CDC's norovirus expert acknowledged that norovirus is resistant to many common disinfectants. The CDC recommends using bleach to kill norovirus.
- 39. In addition, there are more than 100 varieties of HPV, some of which cause common warts on the hands and fingers. HPV is transmitted primarily through skin-to-skin contact, including by contact with someone who is carrying the virus on their hands or fingers or by touching something that someone else touched who carried HPV on their hands.
- BAC is ineffective against HPV. According to a study published by the 40. American Society for Microbiology titled "A Broad-Spectrum Microbicide with Virucidal Activity against Sexually Transmitted Viruses" BAC does not inactivate non-enveloped papillomaviruses, including HPV.
- 41. *Gram-negative bacteria*. Gram-negative bacteria have a double membrane, often with a strong outer membrane, that is not readily penetrated. The Products are ineffective against certain gram-negative bacteria, including pseudomonas aeruginosa, and mycobacteria. In addition, the Products have been found to be ineffective or less effective at denaturing the microbes responsible for COVID-19.
- Pseudomonas aeruginosa causes infections in the blood, respiratory tract 42. infections like pneumonia, and infections in the body following surgery. BAC is substantially ineffective against gram-negative bacteria like P. aeruginosa due to the structure of the outer membrane of the microbe, which strictly restricts larger molecules of BAC.
- 43. There are more than 190 species of mycobacteria, which are responsible for numerous, serious diseases, including tuberculosis. BAC is substantially

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27 28 ineffective against most mycobacteria due to the architecture of the cell wall and lipid content of the bacteria.

- In addition, the Products are not listed on the American Chemistry 44. Council's Center for Biocide Chemistries list of approved Products for fighting COVID-19 and it has been noted that they are less effective at "killing" coronavirus than other disinfectants.
- According to a scripps.org webpage addressing use of hand sanitizer 45. during the COVID-19 pandemic, "[i]f benzalkonium chloride is listed as an active ingredient, the sanitizer is probably alcohol-free, or does not include a high enough percentage of alcohol to ward off the COVID-19 virus."
- 46. According to a study published to the US National Library of Medicine of the National Institutes of Health ("PubMed") in March 2020 titled "Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents," the authors "reviewed the literature on all available information about the persistence of human and veterinary coronaviruses on inanimate surfaces as well as inactivation strategies with biocidal agents used for chemical disinfection, e.g. in healthcare facilities. The analysis of 22 studies reveals that human coronaviruses such as Severe Acute Respiratory Syndrome (SARS) coronavirus, Middle East Respiratory Syndrome (MERS) coronavirus or endemic human coronaviruses (HCoV) can persist on inanimate surfaces like metal, glass or plastic for up to 9 days, but can be efficiently inactivated by surface disinfection procedures with 62-71% ethanol, 0.5% hydrogen peroxide or 0.1% sodium hypochlorite within 1 minute. Other biocidal agents such as 0.05-0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate are less effective." (emphasis added).
- **Spores.** The Products are also ineffective against certain spores that cause 47. disease, such as C. difficile and cryptosporidium
- C. difficile is a major spore forming bacteria, which causes between 15-55% of all diarrheas. C. Difficile have complex layers of spore coats, which render

BAC ineffective against this group of bacteria.

- 49. According to the CDC, within a month of diagnosis, 1 in 11 people over the age of 65 died of a healthcare associated C. difficile infection.
- 50. In addition, according to a publication from the National Center for Biotechnology Information from the U.S. National Library of Medicine, C. difficile is associated with high morbidity and the cost of C. difficile infections is estimated at \$5.4 billion in the United States.
- 51. Cryptosporidium is a genus of protozoan pathogens, which include the giardia parasite and the parasite that causes toxoplasmosis. There are at least 16 established cryptosporidium, at least eight of which have been reported in humans.
- 52. The pathogen causing toxoplasmosis is commonly found in cat litter and undercooked food and is one of the most common parasitic infections in the world, which may be responsible for approximately 40 million infections in the United States.
- 53. Cryptosporidium are responsible for causing gastrointestinal symptoms, including vomiting and diarrhea. Cryptosporidiosis is also the most common cause of recreational water illness outbreaks in the United States. According to the CDC, outbreaks of cryptosporidium increased an average of 13% each year from 2009 to 2017.
- 54. Cryptosporidium is protected by an outer shell that makes it very difficult to kill. Cryptosporidium can, for example, survive for many days in chlorinated water in pools and on surfaces disinfected with chlorine bleach.
- 55. Accordingly, the microbes against which the Products are ineffective, evaluated alone or collectively, account for more than .01% of "germs" and render Defendants' Efficacy Representations false and misleading.
- 56. Furthermore, several studies have noted that BAC may actually increase the incidence of "germs", including because BAC may cause antibacterial resistance in certain microbes.
 - 57. For example, a 2020 publication titled "Effect of sub-lethal chemical

disinfection on the biofilm forming ability, resistance to antibiotics and expression of virulence genes of Salmonella Enteritidis biofilm-surviving cells" the authors examined "in food environments" bacteria that "can survive and present increased virulence/resistance." The authors concluded that: "After BAC (Benzalkonium Chloride) and HP (hydrogen peroxide) exposure, biofilm-derived cells presented a down-regulation of rpoS. Exposure to BAC also revealed an up-regulation of invA, avrA and csgD on Salmonella Enteritidis NCTC 13349. The results obtained suggest that biofilm-derived cells that survive disinfection may represent an increased health risk."

- 58. Although this action is brought pursuant to consumer protection and common law based on Defendants' false and misleading label representations, and not based on any FDA regulation, by way of background it should be noted that in 2019 the FDA issued a Final Rule wherein it deferred any regulatory action for three consumer antiseptic rub ingredients, including BAC.
- 59. The FDA deferred making a monograph or nonmonograph finding for these ingredients and stated that the status would be addressed "after completion and analysis of studies to address the safety and effectiveness data gaps of these ingredients or at another time, if these studies are not completed." Furthermore, the FDA stated that it was deferring a ruling on whether the ingredients, including BAC, are generally recognized as safe and effective ("GRAS/GRAE").
- 60. Accordingly, the Products do not have monograph status, meaning that they are not generally accepted as over-the-counter-drugs and thus are not approved for marketing or labeling under any monograph. Without approval as over-the-counter-drugs and monograph status, there is no generally accepted FDA language for labeling and marketing the Products.

² A monograph is described by the FDA as "a kind of 'recipe book' covering acceptable ingredients, doses, formulations, and labeling in over-the-counter drugs.

B. <u>Defendants Falsely Label and Advertise the Products as</u> "Hypoallergenic" and "Gentle"

- 61. Defendants make numerous false and misleading representations about the hypoallergenic and gentle formulation of the Products.
- 62. On the primary display panel, Defendants state that the Products are "Hypoallergenic." In addition, on the back label, Defendants prominently represent next to an image of a doctor, that the Products are "**Pediatrician Tested**". Defendants also state that the Products are "specially formulated to be tough on dirt and germs, yet gentle on skin" (collectively, the "Skin Safety Representations" and together with the "Efficacy Representations" the "Representations").
- 63. Contrary to the Skin Safety Representations, numerous ingredients in the Products are known allergens or skin irritants.
 - 64. **BAC**, the active ingredient in the Products, is an established skin irritant.
- 65. According to a study, which reviewed Mayo Clinic experience from 2000 to 2012 with patch testing, BAC is increasingly associated with allergic contact dermatitis. The study states that from 2001 through 2005 and 2006 through 2010, BAC was among the top 10 most frequent allergens in the standard series.
- 66. A Swiss study found that 5.5% of people with contact dermatitis were sensitized to BAC.
- 67. A study published by the Int J Med Sci., titled "Effect of the Hand Antiseptic Agents Benzalkonium Chloride, Povidone-Iodine, Ethanol, and Chlorhexidine Gluconate on Atopic Dermatitis in NC/Nga Mice," evaluated the effects of BAC on individuals with atopic dermatitis. The study found that, in a clinical setting involving mice, BAC "induced a significant increase in the severity of the clinical score, infiltration of inflammatory cells, local expression of inflammatory cytokines in subcutaneous tissue, and total serum immunoglobulin."
- 68. BAC has also been found to cause adverse health effects, including the triggering of asthma symptoms in people both with and without a history of asthma, and

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the triggering of respiratory sensitization and asthma that is attributable to hyperresponsiveness and/or inflammation.

- 69. Phenoxyethanol is a known toxin, allergen and a suspected carcinogen. Numerous studies demonstrate that phenoxyethanol can cause DNA mutation in animals.
- 70. The FDA has stated that phenoxyethanol is "a preservative that is primarily used in cosmetics and medications" and that it can "depress the central nervous system and may cause vomiting and diarrhea" in infants.
- In addition, the French Agence Nationale de Securite du Medicament et des 71. *Produits de Sante* has cautioned consumers not to use wipes containing phenoxyethanol on children under the age of three because of health concerns related to "reproductive and developmental toxicity."
- The Material Safety Data Sheet (MSDS) on phenoxyethanol states that it 72. can cause skin and lung irritation, and that it may also be toxic to the kidneys, nervous system, and liver, and repeated, long-term exposure can cause organ damage. The MSDS further states that the toxic effects can occur through inhalation, skin exposure, and ingestion.
- 73. According to Hazard Notifications from the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), phenoxyethanol presents a category 2 danger for skin irritation, a category 4 danger for acute oral toxicity if swallowed, and a category 2A danger for causing serious eye damage or eye irritation.
- Caprylyl glycol is a synthetic skin conditioning agent, preservative and 74. known irritant.
- Dihydroxypropyl peg-5 linoleammonium chloride. According to the 75. PubChem Compound Summary, the GHS information provided by 49 companies demonstrated that the compound does not meet GHS hazard criteria by 36 of the 49 companies. The notifications provided included the warning that the compound causes skin irritation and serious eye irritation.

- 76. **Potassium Sorbate** is a preservative that can cause allergic reactions and skin irritation in skin care products, particularly where it is applied repeatedly or in high concentration.

 77. **Disodium EDTA** a chemical preservative, has been found to disrupt the
- 77. **Disodium EDTA**, a chemical preservative, has been found to disrupt the surface of skin cells so that other chemicals may penetrate skin more easily.
- 78. *Fragrance*. According to the FDA, fragrance is a common allergen found in cosmetic products and can cause allergic contact dermatitis.
- 79. Accordingly, Defendants' Skin Safety Representations are false and misleading.

C. Plaintiff and Consumers Purchased the Products to Their Detriment

- 80. Plaintiff and consumers purchased the Products to their detriment.
- 81. Plaintiff purchased the Products multiple times during the class period in various scents, sizes and configurations, including but not limited to Wet Ones travel packs, singles and canisters, and including in or about March of 2020. Plaintiff purchased the Products for personal and family use, including for use on her son. The price paid by Plaintiff was representative of the price paid by similarly situated consumers who purchased the Products. In addition, the Representations on the Products purchased by Plaintiff were the same as the Representations purchased by members of the Class.
- 82. In purchasing the Products, Plaintiff relied on Defendants' Representations, including that the Products "Kill[] 99.99% of Germs" and that they are hypoallergenic and/or gentle on skin.
- 83. Defendants knew or should have known that reasonable consumers would consider the Representations material in deciding to purchase the Products. Accordingly, Defendants' Representations are false, misleading and reasonably likely to mislead reasonable consumers.
- 84. At the time Plaintiff purchased the Products, Plaintiff did not know, and had no reason to know, that the Representations were misleading, deceptive and

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unlawful. Plaintiff would not have purchased the Products, or would have purchased them on different terms, if she had known the truth.

It is possible, however, that Plaintiff would purchase the Products in the 85. future if the Representations were truthful.

CLASS DEFINITION AND CLASS ALLEGATIONS

86. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of herself, on behalf of all others similarly situated, and as a member of the Classes defined as follows (collectively, the "Class"):

> All citizens of the United States who, within the relevant statute periods, purchased Defendants' limitations **Products** ("Nationwide Class");

> All citizens of California who, within four years prior to the filing of the initial Complaint, purchased Defendants' Products ("California Subclass").

- Excluded from the Class are: (i) Defendants, their assigns, successors, and 87. legal representatives; (ii) any entities in which Defendants have a controlling interest; (iii) federal, state, and/or local governments, including, but not limited to, their departments, agencies, divisions, bureaus, boards, sections, groups, counsels, and/or subdivisions; (iv) all persons presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and (v) any judicial officer presiding over this matter and person within the third degree of consanguinity to such judicial officer.
- 88. Plaintiff reserves the right to amend or otherwise alter the class definition presented to the Court at the appropriate time, or to propose or eliminate sub-classes, in response to facts learned through discovery, legal arguments advanced by Defendants, or otherwise.
- 89. This action is properly maintainable as a class action pursuant to Federal Rule of Civil Procedure 23 for the reasons set forth below.

- 90. <u>Numerosity</u>: Members of the Class are so numerous that joinder of all members is impracticable. Upon information and belief, the Nationwide Class consists of millions of purchasers dispersed throughout the United States, and the California Subclass consists of hundreds of thousands of purchasers throughout the State of California. Accordingly, it would be impracticable to join all members of the Class before the Court.
- 91. <u>Common Questions Predominate:</u> There are numerous and substantial questions of law or fact common to all members of the Class that predominate over any individual issues. Included within the common questions of law or fact are:
 - Whether the Product Representations and omissions are, or any single representation or omission is, false, misleading and/or deceptive;
 - Whether Defendants engaged in unlawful, unfair or deceptive business practices by advertising and selling the Products;
 - Whether Defendants violated California Bus. & Prof. Code § 17200, et seq.; Cal. Bus. & Prof. Code § 17500, et seq.; and/or the Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.;
 - Whether Defendants committed a breach of express warranty;
 - Whether Plaintiff and the Class are entitled to equitable and/or injunctive relief;
 - Whether Plaintiff and the Class have sustained damage as a result of Defendants' unlawful conduct;
 - The proper measure of damages sustained by Plaintiff and the Class; and
 - Whether Defendants were unjustly enriched by their unlawful practices.
- 92. <u>Typicality</u>: Plaintiff's claims are typical of the claims of the members of the Class she seeks to represent because Plaintiff, like the Class members, purchased Defendants' misbranded Products. Defendants' unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were experienced. Plaintiff and the Class sustained similar injuries arising

out of Defendants' conduct. Plaintiff's and Class member's claims arise from the same practices and course of conduct and are based on the same legal theories.

- 93. Adequacy: Plaintiff is an adequate representative of the Class she seeks to represent because her interests do not conflict with the interests of the members of the Class Plaintiff seeks to represent. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel experienced and competent in the prosecution of complex class actions, including complex questions that arise in consumer protection litigation.
- 94. <u>Superiority and Substantial Benefit</u>: A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all members of the Class is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:
 - a. The claims presented in this case predominate over any questions of law or fact, if any exists at all, affecting any individual member of the Class;
 - b. Absent a Class, the members of the Class will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants profit from and enjoy their ill-gotten gains;
 - c. Given the size of individual Class members' claims, few, if any, members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent members have no substantial interest in individually controlling the prosecution of individual actions;
 - d. When the liability of Defendants has been adjudicated, claims of all members of the Class can be administered efficiently and/or determined uniformly by the Court; and

- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and members of the Class can seek redress for the harm caused to them by Defendants.
- 95. Because Plaintiff seeks relief for all members of the Class, the prosecution of separate actions by individual members would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendants.
- 96. The prerequisites to maintaining a class action for injunctive or equitable relief pursuant to Fed. R. Civ. P. 23(b)(2) are met as Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or equitable relief with respect to the Class as a whole.
- 97. The prerequisites to maintaining a class action pursuant to Fed. R. Civ. P. 23(b)(3) are also met as questions of law or fact common to Class members predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.
- 98. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Unfair and Unlawful Business Acts and Practices (Business and Professions Code § 17200, et seq.) (forPlaintiff and the California Subclass)

- 99. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint, as though fully set forth herein.
- 100. Defendants' conduct constitutes an unfair business act and practice pursuant to California Business & Professions Code §§ 17200, *et seq*. (the "UCL"). The UCL provides, in pertinent part: "Unfair competition shall mean and include unlawful,

unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising"

- 101. Plaintiff brings this claim seeking equitable and injunctive relief to stop Defendants' misconduct, as complained of herein, and to seek restitution of the amounts Defendants acquired through the unfair, unlawful, and fraudulent business practices described herein.
- 102. Defendants' knowing conduct, as alleged herein, constitutes an "unfair" and/or "fraudulent" business practice, as set forth in California Business & Professions Code §§ 17200-17208.
- 103. Defendants' conduct was and continues to be unfair and fraudulent because, directly or through its agents and employees, Defendants made uniform materially false representations and omissions.
- 104. Defendants knowingly and intentionally made the Representations which, as described herein, are false and misleading because the Products do not "kill 99.99% of germs" and are not hypoallergenic and/or gentle on skin.
- 105. Defendants also made materially false representations and omissions by failing to disclose the truth about the Products, including that the Products do not denature certain microbes and that they contain ingredients that are known irritants and/or allergens.
- 106. Defendants are aware that their Representations and omissions were and continue to be false and misleading.
- 107. Defendants had an improper motive—to derive financial gain at the expense of accuracy or truthfulness—in their practices related to the labeling and advertising of the Products.
- 108. There were reasonable alternatives available to Defendants to further their legitimate business interests, other than the conduct described herein.
- 109. Defendants' misrepresentations of material facts, as set forth herein, also constitute an "unlawful" practice because they violate California Civil Code §§ 1572,

1573, 1709, 1710, 1711, and 1770 and the laws and regulations cited herein, as well as the common law.

- 110. Defendants' conduct in making the Representations and omissions described herein constitutes a knowing failure to adopt policies in accordance with and/or adherence to applicable laws, as set forth herein, all of which are binding upon and burdensome to their competitors. This conduct engenders an unfair competitive advantage for Defendants, thereby constituting an unfair business practice under California Business & Professions Code §§ 17200-17208.
- 111. In addition, Defendants' conduct was, and continues to be, unfair in that their injury to countless purchasers of the Products is substantial, and is not outweighed by any countervailing benefits to consumers or to competitors.
- 112. Moreover, Plaintiff and members of the California Subclass could not have reasonably avoided such injury. Defendants' uniform, material misrepresentations and omissions regarding the Products were likely to deceive, and Defendants knew or should have known that their misrepresentations and omissions were untrue and misleading. Plaintiff purchased the Products in reliance on the Representations made by Defendants, including that the Product labeling was accurate, and without knowledge of Defendants' misrepresentations and omissions.
- 113. Plaintiff and members of the California Subclass have been directly and proximately injured by Defendants' conduct in ways including, but not limited to, the monies paid to Defendants for the Products, interest lost on those monies, and consumers' unwitting support of a business enterprise that promotes deception and undue greed to the detriment of consumers, such as Plaintiff and California Subclass members.
- 114. As a result of the business acts and practices described above, Plaintiff and members of the California Subclass, pursuant to § 17203, are entitled to an Order enjoining such future wrongful conduct on the part of Defendants and such other Orders and judgments that may be necessary to disgorge Defendants' ill-gotten gains and to

restore to any person in interest any money paid for the Products as a result of the wrongful conduct of Defendants.

115. Pursuant to Civil Code § 3287(a), Plaintiff and the California Subclass are further entitled to pre-judgment interest as a direct and proximate result of Defendants' unfair and fraudulent business conduct. The amount on which interest is to be calculated is a sum certain and capable of calculation, and Plaintiff and the California Subclass are entitled to interest in an amount according to proof.

SECOND CAUSE OF ACTION Deceptive Advertising Practices (California Business & Professions Code §§ 17500, et seq.) (for Plaintiff and the California Subclass)

- 116. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint, as though fully set forth herein.
- 117. California Business & Professions Code § 17500 prohibits "unfair, deceptive, untrue or misleading advertising"
- 118. Defendants violated § 17500 when they represented, through their false and misleading Representations and omissions, that Defendants' Products possessed characteristics and value that they did not actually have. Defendants knowingly and intentionally made the Representations which, as described herein, are false and misleading because the Products do not "kill[] 99.99% of germs" and are not hypoallergenic and/or gentle on skin.
- 119. Defendants also made materially false representations and omissions by failing to disclose the truth about the Products, including that the Products do not denature certain microbes and that they contain ingredients that are known irritants and/or allergens.
- 120. Defendants' deceptive practices were designed to induce reasonable consumers like Plaintiff to purchase the Products. Defendants' uniform, material misrepresentations and omissions regarding the Products were likely to deceive, and Defendants knew or should have known that their uniform misrepresentations and

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omissions were untrue and/or misleading. Plaintiff purchased the Products in reliance on the Representations made by Defendants, including that the Product labeling was accurate, and without knowledge of Defendants' misrepresentations and omissions.

- 121. Plaintiff and members of the California Subclass have been directly and proximately injured by Defendants' conduct in ways including, but not limited to, the monies paid to Defendants for the Products, interest lost on those monies, and consumers' unwitting support of a business enterprise that promotes deception and undue greed to the detriment of consumers, such as Plaintiff and Subclass members.
- 122. The above acts of Defendants were and are likely to deceive reasonable consumers in violation of § 17500.
- 123. In making the statements and omissions alleged herein, Defendants knew or should have known that the statements and representations were untrue or misleading, and acted in violation of § 17500.
- 124. Defendants continue to engage in unlawful, unfair and deceptive practices in violation of §17500.
- 125. As a direct and proximate result of Defendants' unlawful conduct in violation of § 17500, Plaintiff and members of the California Subclass, pursuant to § 17535, are entitled to an Order of this Court enjoining such future wrongful conduct on the part of Defendants, and requiring Defendants to disclose the true nature of their misrepresentations and omissions.
- 126. Plaintiff and members of the California Subclass also request an Order requiring Defendants to disgorge their ill-gotten gains and/or award full restitution of all monies wrongfully acquired by Defendants by means of such acts of false advertising, plus interests and attorneys' fees.

THIRD CAUSE OF ACTION **Consumer Legal Remedies Act** (Cal. Civ. Code § 1750, et seq.) (for Plaintiff and the California Subclass)

127. Plaintiff re-alleges and incorporates by reference the allegations contained

in the preceding paragraphs of this complaint, as though fully set forth herein.

- 128. Plaintiff brings this action pursuant to California's Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750, et seq.
- 129. The CLRA provides that "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer are unlawful."
- 130. The Products are "goods," as defined by the CLRA in California Civil Code §1761(a).
- 131. Defendants are a "person," as defined by the CLRA in California Civil Code §1761(c).
- 132. Plaintiff and members of the California Subclass are "consumers," as defined by the CLRA in California Civil Code §1761(d).
- 133. Purchase of the Products by Plaintiff and members of the California Subclass are "transactions," as defined by the CLRA in California Civil Code §1761(e).
- 134. Defendants violated Section 1770(a)(5) by representing that the Products have "characteristics, . . . uses [or] benefits . . . which [they] do not have" in that the Products are falsely and misleadingly labeled and represented, as described herein.
- 135. Similarly, Defendants violated section 1770(a)(7) by representing that the Products "are of a particular standard, quality, or grade . . . if they are of another" by making the Representations and omissions described herein.
- 136. In addition, Defendants violated section 1770(a)(9) by advertising the Products "with intent not to sell them as advertised" in that the Products are misrepresented and misbranded as described herein.
- 137. Defendants' uniform, material, misrepresentations and omissions regarding the Products were likely to deceive, and Defendants knew or should have known that their misrepresentations and omissions were untrue and misleading.
- 138. Plaintiff and members of the California Subclass could not have reasonably avoided injury. Plaintiff and members of the California Subclass were unaware of the

existence of facts that Defendants suppressed and failed to disclose and Plaintiff and members of the California Subclass would not have purchased the Products and/or would have purchased them on different terms had they known the truth.

- 139. Plaintiff and members of the California Subclass have been directly and proximately injured by Defendants' conduct. Such injury includes, but is not limited to, the purchase price of the Products and/or the price of the Products at the prices at which they were offered.
- 140. Given that Defendants' conduct violated § 1770(a)(5), Plaintiff and members of the California Subclass are entitled to seek and seek injunctive relief to put an end to Defendants' violations of the CLRA.
- 141. Moreover, Defendants' conduct is malicious, fraudulent, and wanton in that Defendants intentionally misled and withheld material information from consumers to increase the sale of the Products.
- 142. Pursuant to California Civil Code § 1782(a), on March 18, 2020, Plaintiff on her own behalf, and on behalf of members of the California Subclass, notified Defendants of the alleged violations of the Consumer Legal Remedies Act by letter setting forth Plaintiff's claims. Despite giving Defendants more than 30-days from the date of the notification letter to provide appropriate relief for violations of the CLRA, Defendants have failed to provide any such relief. As such, Plaintiff also seeks compensatory, monetary and punitive damages, in addition to equitable and injunctive relief, and requests that this Court enter such Orders or judgments as may be necessary to restore to any person in interest any money which may have been acquired by means of such unfair business practices, and for such other relief as is provided in California Civil Code § 1780 and in the Prayer for Relief.
- 143. Plaintiff further requests pursuant to § 1780(a)(2) that the Court enjoin Defendants from continuing to employ the unlawful methods, acts, and practices alleged herein.

FOURTH CAUSE OF ACTION

Breach of Express Warranty

(for Plaintiff, the Nationwide Class, and California Subclass)

- 144. Plaintiff re-alleges and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint, as though fully set forth herein.
- 145. By advertising and selling the Products at issue, Defendants made promises and affirmations of fact on the Products' packaging and labeling, as described herein. This labeling and advertising constitutes express warranties and became part of the basis of the bargain between Plaintiff and members of the Class, and Defendants.
- 146. Defendants, through their advertising and labeling, created express warranties that the Products comport with the Representations. Specifically, Defendants created express warranties that the Products satisfy the Efficacy and Skin Safety Representations, including that the Products kill 99.99% of germs and are hypoallergenic and/or gentle on skin.
- 147. The express warranties appear on all Product labels and specifically relate to the goods being sold.
- 148. Despite Defendants' express warranties about the nature of the Products, the Products do not comport with the Representations. Thus, the Products were and are not what Defendants represented them to be.
- 149. Accordingly, Defendants breached express warranties about the Products and their qualities because the Products do not conform to Defendants' affirmations and promises.
- 150. Plaintiff provided Defendants with pre-suit notice of the breach of warranty, including by letter dated March 18, 2020.
 - 151. Plaintiff and members of the Class purchased the Products.
- 152. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and members of the Class were harmed in the amount of the purchase price they paid for the Products. Further, Plaintiff and members of the Class have suffered and continue to suffer economic losses and other general and specific damages including,

but not limited to, the amounts paid for the Products, and any interest that would have accrued on those monies, in an amount to be proven at trial.

FIFTH CAUSE OF ACTION QUASI-CONTRACT

(for Plaintiff, the Nationwide Class and California Subclass)

- 153. Plaintiff repeats and re-alleges the allegations of the preceding paragraphs as if fully set forth herein.
- 154. By purchasing the Products, Plaintiff and members of the Class conferred a benefit on Defendants in the form of the purchase price of the Products.
 - 155. Defendants had knowledge of such benefits.
- 156. Defendants appreciated the benefit because, were consumers not to purchase the Products, Defendants would not generate revenue from the sales of the Products.
- 157. Defendants' acceptance and retention of the benefit is inequitable and unjust because the benefit was obtained by Defendants' fraudulent and misleading Representations and omissions and unlawful conduct.
- 158. Equity cannot in good conscience permit Defendants to be economically enriched for such actions at the expense of Plaintiff and members of the Class, and therefore restitution and/or disgorgement of such economic enrichment is required

PRAYER

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, prays for judgment against Defendants as follows:

- A. For an order certifying the Nationwide Class and the California Subclass under Rule 23 of the Federal Rules of Civil Procedure; naming Plaintiff as representative of the Nationwide Class and California Subclass; and naming Plaintiff's attorneys as Class Counsel to represent the Class and California Subclass;
- B. For an order declaring that Defendants' conduct violates the statutes and laws referenced herein;

1	C. Fo	or an order	awarding, a	s appropriate,	compensatory	and mo	netary		
2	damages, resti	tution or disg	orgement to P	laintiff and the	Class for all cau	ises of ac	ction;		
3	D. F	or an order r	equiring Defe	endants to imm	nediately cease a	nd desis	t from		
4	selling their r	misbranded I	Products in v	iolation of lav	w; enjoining De	efendants	from		
5	continuing to label, market, advertise, distribute, and sell the Products in the unlawful								
6	manner described herein; and ordering Defendants to engage in corrective action;								
7	E. For an order awarding attorneys' fees and costs;								
8	F. Fe	or an order av	warding puniti	ve damages;					
9	G. Fo	or an order av	warding pre-ai	nd post-judgme	ent interest; and				
10	H. F	or such other	and further re	lief as the Cou	rt deems just and	l proper.			
11	DATED. L.1.	- 21 2020	17		IID				
12	DATED: July	7 31, 2020	KA	AMBERLAW	, LLP				
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Naomi Spector (SBN 222573) 1 Email: nspector@kamberlaw.com 2 KAMBERLAW, LLP 1501 San Elijo Road South, Ste. 104 3 San Marcos, CA 92078 4 Phone: 310.400.1053 Fax: 212.202.6364 5 6 Counsel for Plaintiff Lauren Souter, and the putative Classes 7 8 IN THE UNITED STATES DISTRICT COURT 9 FOR THE SOUTHERN DISTRICT OF CALIFORNIA 10 LAUREN SOUTER, individually, **CASE NO. 20-CV-1486 TWR (BLM)** 11 and on behalf of others similarly 12 situated, FIRST AMENDED CLASS ACTION **COMPLAINT FOR:** 13 Plaintiff. 14 1. UNFAIR AND UNLAWFUL VS. **BUSINESS ACTS AND PRACTICES** 15 (CAL. BUS & PROF. CODE §17200 ET 16 EDGEWELL PERSONAL CARE SEQ.); COMPANY, EDGEWELL 2. DECEPTIVE ADVERTISING 17 PERSONAL CARE BRANDS LLC, PRACTICES (CAL. BUS & PROF. and EDGEWELL PERSONAL 18 CARE, LLC, **CODE §§ 17500, ET SEQ.)**; 3. CONSUMER LEGAL REMEDIES 19 Defendants. ACT (CAL. CIV. CODE § 1750, ET 20 SEQ.); 4. BREACH OF EXPRESS 21 WARRANTY; AND 22 5. QUASI-CONTRACT. 23 **DEMAND FOR JURY TRIAL** 24 25 Pursuant to this Court's Order Granting Defendants' Motion to Dismiss [Dkt. No. 26 54] Plaintiff Lauren Souter on behalf of herself and others similarly situated, by and 27 through her undersigned counsel, hereby files this First Amended Class Action 28

CLASS ACTION COMPLAINT

Complaint against Defendants Edgewell Personal Care Company, Edgewell Personal Care Brands, LLC, and Edgewell Personal Care, LLC (collectively "Defendants") and states as follows:

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NATURE OF THE ACTION

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1. This is a case about holding the manufacturers of Wet Ones hand wipes¹ responsible for truthfully and accurately labeling their Products, which are used and relied on by consumers to keep themselves and their families safe from germs.

- 2. Specifically, Plaintiff alleges that Defendants' label representations concerning the efficacy and skin safety of the Products are false and misleading, including Defendants' representations that the Products "Kill[] 99.99% of Germs" and that they are hypoallergenic and gentle on skin. Plaintiff also asserts that Defendants omit critical information concerning the limitations of the Products to "kill germs."
- 3. "Germs" is a commonly understood term as an organism that causes disease.
- 4. Contrary to Defendants' material representations, however, the Products do not "kill" 99.99% of the organisms that cause disease.
- As described in detail herein, the active ingredient in the Products, 5. benzalkonium chloride ("BAC"), is ineffective against non-enveloped viruses, certain gram negative bacteria, and spores. In addition, the concentration of BAC in the Products and manner of application render the Products ineffective to "kill" certain "germs."
- 6. According to studies, hand sanitizers such as the Products are tested under optimal laboratory conditions, which cannot imitate a real-world setting. Accordingly, laboratory findings that hand sanitizers kill 99.99% of germs do not translate to actual

¹ Wet Ones wipes are sold in a variety of sizes, scents and variations, including Wet Ones canisters, travel packs, singles and big ones (collectively, the "Products"). This action includes in the definition of Products all sizes, scents and variations of the Products that bear the "Kills 99.99% of Germs" representation and have Benzalkonium Chloride as the active ingredient.

use, where the products kill far less than 99.99% of germs.

- 7. In one study conducted among eighth grade students, for example, three popular hand sanitizer brands were found to kill between 46% to 60% of microbes—a far cry from the 99.99% kill rate that is touted by Defendants.
- 8. Reasonable consumers, however, are misled and deceived by Defendants' label representations, including the prominent front panel statement that the Products "Kill[] 99.99% of Germs".
- 9. Reasonable consumers are also misled and deceived by Defendants' label representations that the Products are "Hypoallergenic" and gentle where numerous ingredients in the Products, including the active ingredient, are significant allergens and skin irritants.
- 10. Plaintiff and reasonable consumers purchased the Products and paid a price premium for them based on Defendants' label representations.
- 11. Plaintiff and consumers are and were deprived of the benefit of the bargain because, contrary to Defendants' express and prominent label statements, the Products do not in fact kill 99.99% of germs and are not hypoallergenic.
- 12. Plaintiff, would not have purchased the Products if she knew that the label representations were false, or would have purchased them on different terms.
- 13. Plaintiff brings this action individually and on behalf of those similarly situated and seeks to represent a Nationwide Class and California Subclass (defined *infra*.). Plaintiff seeks damages, interest thereon, reasonable attorneys' fees and costs, restitution, equitable relief, and disgorgement of all benefits Defendants have enjoyed from their unlawful and/or deceptive business practices, as detailed herein. In addition, Plaintiff seeks injunctive relief to stop Defendants' unlawful conduct in the labeling and marketing of the Products. Plaintiff makes these allegations based on her personal knowledge as to herself and her own acts and observations and, otherwise, on information and belief based on investigation of counsel.

JURISDICTION AND VENUE

- 14. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed classes; (2) members of the proposed classes have a different citizenship from Defendants; and (3) the claims of the proposed class members exceed \$5,000,000 in the aggregate.
- 15. This Court has personal jurisdiction over Defendants because Defendants' contacts with the forum are continuous and substantial, and Defendants intentionally availed themselves of the markets within California through their sale and distribution of the Products to California consumers and through the privilege of conducting business in California.
- 16. Venue is proper in this District pursuant to 28 U.S.C. §1391(b) because Defendants engage in continuous and systematic business activities within the State of California. Moreover, a substantial part of the events and omissions giving rise to the claims alleged herein occurred in this District. *See also* Declaration of Lauren Souter Regarding Venue Pursuant to Cal. Civ. Code § 1780(d), attached hereto as Exhibit A.

PARTIES

- 17. Plaintiff Lauren Souter is a resident of San Diego, California, who purchased the Products during the class period, as described herein. Plaintiff's claim is typical of all Class members in this regard. In addition, the advertising and labeling on the package of the Products purchased by Plaintiff, including the Products' label representations, is typical of the advertising, labeling and representation of the Products purchased by members of the Classes.
- 18. Defendant Edgewell Personal Care Company is a Missouri corporation with its principal place of business in Shelton, CT. Defendant and its agents manufacture, market, distribute, label, promote, advertise and sell the Products. At all times material hereto Defendant was conducting business in the United States, including in California, through its services as a manufacturer and supplier to various stores in

- 19. Defendant Edgewell Personal Care Brands, LLC is a Delaware Limited Liability Company with its principal place of business in Shelton, CT. Defendant and its agents manufacture, market, distribute, label, promote, advertise and sell the Products. At all times material hereto Defendant was conducting business in the United States, including in California, through its services as a manufacturer and supplier to various stores in California and by, among other things, maintaining agents for the customary transaction of business in California.
- 20. Defendant Edgewell Personal Care, LLC is a Delaware Limited Liability Company with its principal place of business in Shelton, CT. Defendant and its agents manufacture, market, distribute, label, promote, advertise and sell the Products. At all times material hereto Defendant was conducting business in the United States, including in California, through its services as a manufacturer and supplier to various stores in California and by, among other things, maintaining agents for the customary transaction of business in California.
- 21. Defendants and their agents promoted, marketed and sold the Products at issue in this jurisdiction and in this judicial district. The unfair, unlawful, deceptive, and misleading advertising and labeling of the Products was prepared and/or approved by Defendants and their agents, and was disseminated by Defendants and their agents through labeling and advertising containing the misrepresentations and omissions alleged herein.

FACTUAL ALLEGATIONS

A. Defendants Falsely Label the Products as Killing 99.99% of Germs

- 22. Defendants manufacture, label, market, promote, advertise, and sell the Products.
- 23. The following images depict the front and back panel representations on the Products:





- 24. Defendants make numerous false and misleading representations about the ability of the Products to kill germs and clean hands.
- 25. Defendants prominently state on the primary display panel that the Products "Kill[] 99.99% of Germs". On the back panel, Defendants state that "Wet Ones® **Antibacterial** Hand Wipes kill 99.99% of germs and wipe away dirt, providing a better clean than hand sanitizers. They are specially formulated to be tough on dirt and germs, yet gentle on skin, so you can confidently keep your hands fresh and clean when soap and water are not available." (Collectively, the "Efficacy Representations").
- 26. Under "Directions" Defendants state that "adults and children 2 years and over" should "apply to hands" and "allow skin to dry without wiping".
- 27. Defendants' Efficacy Representations are false, deceptive and materially misleading.
- 28. Germs" is defined by Merriam-Webster as, among other things, "especially: a microorganism causing disease".

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- 29. The active ingredient in the Products, BAC, does not "kill" certain microorganisms causing disease, which comprise more than .01% of "germs."
- 30. In addition, the concentration and formulation of the active ingredient-.13% BAC on a hand wipe—does not "Kill[] 99.99% of Germs".
- 31. The directions also demonstrate that the Products are ineffective as they state "apply to hands" and "allow skin to dry without wiping." BAC, however, is slow to act, meaning that it generally must remain on hands for more time than soap and water or an alcohol-based hand sanitizer to "kill germs." In many instances, the Product will not remain on hands for a sufficient amount of time for the active ingredient to kill certain germs.
- 32. Furthermore, hands that are dirty, greasy or grimy prevent adequate application or saturation of the product.
- In purchasing the Products, Plaintiff relied on Defendants' Efficacy 33. Representations.
- 34. Among other things, Plaintiff reasonably relied on Defendants' Efficacy Representations for the truth of the matter stated—that the Products kill 99.99% of germs.
- 35. To be clear, Plaintiff does not claim that the Products failed to protect her or her family from any specific type of "germ" or organism.
- 36. Instead, Plaintiff contends that, had she known that the Efficacy Representations were false, she would not have purchased the Products at all, or would have paid less for them.
- Accordingly, Plaintiff provides the following information concerning the 37. limitations of the Products to kill certain microorganisms to demonstrate the falsity of Defendants' Efficacy Representations.

1. BAC Is Ineffective Against Numerous Germs

38. BAC belongs to a group of chemicals called quaternary ammonium compounds ("QAC").

- 39. BAC generally works by denaturing the proteins in a cell, including by absorbing or disrupting the cytoplasmic membrane, which causes vital substances to leak out of the cell. By this mechanism, the cell structure can be compromised, resulting in damage, disruption of essential cell processes and/or cell death. Accordingly, the outer structure of the microbe to which BAC is applied is critically important to whether BAC will be effective to denature or destroy that microbe.
- 40. According to an information page published by the CDC titled "Hand Hygiene Recommendations Guidance for Healthcare Providers about Hand Hygiene and COVID-19" (updated May 17, 2020), "CDC does not have a recommended alternative to hand rub products with greater than 60% ethanol or 70% isopropanol as active ingredients. Benzalkonium chloride, along with both ethanol and isopropanol, is deemed eligible by FDA for use in the formulation of healthcare personnel hand rubs.[2] However, available evidence indicates benzalkonium chloride has less reliable activity against certain bacteria and viruses than either of the alcohols." *See* https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html (footnote omitted).
- 41. According to a table published by the Center for Food Security & Public Health regarding the antimicrobial activity of certain disinfectant chemical classes, QAC disinfectants (which includes BAC) demonstrate no activity against: (i) pseudomonads (a type of gram-negative bacteria that are difficult to remove from food preparation surfaces); (ii) chlamydiae (gram-negative bacteria causing infection); (iii) non-enveloped viruses (viruses that lack a lipid bilayer); (iv) parvoviruses (DNA viruses, some of which cause infection in humans, such as "fifth disease"); (v) acid-fast bacteria (a group of bacteria classified by the ability to resist decolorization by acids for staining procedures; for example, M. tuberculosis), (vi) bacterial spores (a dormant form of bacteria; for example, C. difficile, described below), (vii) coccidia (causing infection in dogs), and (viii) prions (proteins with the ability to transmit their misfolded shape onto other proteins and which are responsible for several fatal neurodegenerative

diseases in humans):

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2 This table provides general information for selected disinfectant The Antimicrobial Spectrum of Disinfectants chemical classes. Antimicrobial activity may vary with formulation 3 and concentration. The use of tidde numes does not in ally way signify endorsement of a particular product. They are provided as examples Removal of greanic material 4 Permayagena must always precede the use Amaio of any disinfectant. Acida 5 most susceptible 6 gram-positive bacteria 7 susceptibility of microorganisms to chemical disinfectants 8 richettsiae enveloped viruses 9 chlamydiae 10 non-enveloped viruses 11 disprnaviruses (Le. FMD) 12 parvoviruses acid-fasi bacteria 13 bacterial spores 14 15 5 - personal cacio is spendicial - composition formation 3-come have schooly against coccide no activity most resistant affective information not available 16 limited activity ans ard Prastic of Dulmhellon. Preservator and Standardon. St. etc., 2016. Annes, M. Witer-Bladowski, McCennel. 2007. SEM Prast. Mantanger (EC. Bulate Wil. Wieser D., Heathstan infection Control Practicus Advancy Committee 17

- 42. Specifically, the structure of non-enveloped viruses, certain gram negative bacteria, and spores render BAC substantially ineffective because BAC cannot readily permeate or disturb the cell membrane and process.
- 43. *Non-enveloped viruses.* The Products are substantially ineffective at "killing" non-enveloped viruses, including (i) norovirus, (ii) poliovirus, (iii) polyomavirus, (iv) human papillomavirus, and (v) picornavirus.
- 44. There are numerous strains or types of each of these groups of nonenveloped viruses, which are responsible for tens of millions of cases of infection in the United States each year.
- For example, there are approximately 25 different strains of norovirus that affect humans. According to the CDC, each year on average in the United States,

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- norovirus causes 19 to 21 million cases of vomiting and diarrhea illness, including 2,270,000 outpatient clinic visits (mostly in young children), 465,000 emergency room visits (mostly in young children), 109,000 hospitalizations, and 900 deaths (mostly in adults 65 and older). *See* https://www.cdc.gov/norovirus/trends-outbreaks/burden-US.html.
- 46. Norovirus can be found in food settings and on surfaces. Wiping hands or surfaces that are contaminated with norovirus with the Products will not kill the virus.
- 47. According to the CDC, hand washing with soap and water is more effective than hand sanitizing at removing certain kinds of germs, including norovirus. In fact, the CDC's norovirus expert acknowledged that norovirus is resistant to many common disinfectants. The CDC recommends using bleach to kill norovirus. *See* https://www.cdc.gov/norovirus/about/prevention.html.
- 48. In addition, there are more than 100 varieties of HPV, some of which cause common warts on the hands and fingers. HPV is transmitted primarily through skin-to-skin contact, including by contact with someone who is carrying the virus on their hands or fingers or by touching something that someone else touched who carried HPV on their hands. *See* Harvard Health Publishing, Harvard Medical School: Human Papilloma Virus (HPV): health.harvard.edu/a_to_z/human-papilloma-virus-hpv-a-to-z, attached as Exhibit B.
- 49. BAC is ineffective against HPV. According to a study published by the American Society for Microbiology titled "A Broad-Spectrum Microbicide with Virucidal Activity against Sexually Transmitted Viruses" BAC does not inactivate non-enveloped papillomaviruses, including HPV. *See* https://journals.asm.org/doi/full/10.1128/AAC.43.2.314.
- 50. <u>Gram-negative bacteria</u>. Gram-negative bacteria have a double membrane, often with a strong outer membrane, that is not readily penetrated. The Products are ineffective against certain gram-negative bacteria, including pseudomonas aeruginosa, and mycobacteria.

- 51. Pseudomonas aeruginosa causes infections in the blood, respiratory tract infections like pneumonia, and infections in the body following surgery.
- 52. Pseudomonas infection can be transmitted by hands. The best way to prevent infection is to wash hands often. *See* https://www.webmd.com/a-to-z-guides/pseudomonas-infection.
- 53. BAC is substantially ineffective against gram-negative bacteria like P. aeruginosa due to the structure of the outer membrane of the microbe, which strictly restricts larger molecules of BAC.
- 54. There are more than 190 species of mycobacteria, which are responsible for numerous, serious diseases, including tuberculosis. BAC is substantially ineffective against most mycobacteria due to the architecture of the cell wall and lipid content of the bacteria.
- 55. <u>Coronovirus</u>. In addition, the Products have been found to be ineffective or less effective at denaturing the microbes responsible for COVID-19.
- 56. The Products are not listed on the American Chemistry Council's Center for Biocide Chemistries list of approved Products for fighting COVID-19 and it has been noted that they are less effective at "killing" coronavirus than other disinfectants.
- 57. According to a scripps.org webpage addressing use of hand sanitizer during the COVID-19 pandemic, "[i]f benzalkonium chloride is listed as an active ingredient, the sanitizer is probably alcohol-free, or does not include a high enough percentage of alcohol to ward off the COVID-19 virus." *See* https://www.scripps.org/news_items/6991-handwashing-or-hand-sanitizer.
- 58. According to a study published to the US National Library of Medicine of the National Institutes of Health ("PubMed") in March 2020 titled "Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents," the authors "reviewed the literature on all available information about the persistence of human and veterinary coronaviruses on inanimate surfaces as well as inactivation strategies with biocidal agents used for chemical disinfection, e.g. in healthcare

- **Spores.** The Products are also ineffective against certain spores that cause disease, such as C. difficile and cryptosporidium
- C. difficile is a major spore forming bacteria, which causes between 15-60. 55% of all diarrheas. C. Difficile have complex layers of spore coats, which render BAC ineffective against this group of bacteria.

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- According to the CDC, "If someone with C. diff (or caring for someone 61. with C. diff) doesn't clean their hands with soap and water after using the bathroom, they can spread the germs to everything they touch." See https://www.cdc.gov/cdiff/prevent.html#:~:text=diff%20germs%20are%20carried%20 from, germs% 20to% 20everything% 20they% 20touch.
- Furthermore, "when someone else touches the . . . surfaces that person 62. touched, they can pick up the germs on their hands." *Id*.
- Washing with soap and water is the only way to prevent the spread of C. 63. diff. Id.
- According to the CDC, within a month of diagnosis, 1 in 11 people over 64. the age of 65 died of a healthcare associated C. difficile infection.
- In addition, according to a publication from the National Center for 65. Biotechnology Information from the U.S. National Library of Medicine, C. difficile is associated with high morbidity and the cost of C. difficile infections is estimated at \$5.4 billion in the United States.

- 66. Cryptosporidium is a genus of protozoan pathogens, which include the giardia parasite and the parasite that causes toxoplasmosis. There are at least 16 established cryptosporidium, at least eight of which have been reported in humans.
- 67. The pathogen causing toxoplasmosis is commonly found in cat litter and undercooked food and is one of the most common parasitic infections in the world, which may be responsible for approximately 40 million infections in the United States.
- 68. According to the CDC, toxoplasmosis can be transmitted from cats to humans if, for example, a human touches something that has come into contact with a cat feces that contains toxoplasma, including after cleaning a litter box. *See* https://www.cdc.gov/parasites/toxoplasmosis/epi.html.
- 69. Cryptosporidium are responsible for causing gastrointestinal symptoms, including vomiting and diarrhea. Cryptosporidiosis is also the most common cause of recreational water illness outbreaks in the United States. According to the CDC, outbreaks of cryptosporidium increased an average of 13% each year from 2009 to 2017.
- 70. Cryptosporidium is protected by an outer shell that makes it very difficult to kill. Cryptosporidium can, for example, survive for many days in chlorinated water in pools and on surfaces disinfected with chlorine bleach.
- 71. Human hands can be contaminated by cryptosporidium in a number of ways, including by touching surfaces or objects (such as bathroom fixtures or toys) that are contaminated, or by changing diapers or caring for an infected person. *See* https://www.health.ny.gov/diseases/communicable/cryptosporidiosis/fact_sheet.htm#:~ :text=Hands%20can%20become%20contaminated%20in,Contact%20with%20an%20infected%20animal.
- 72. Accordingly, the microbes against which the Products are ineffective, and which are transmitted by human hands, account for more than .01% of "germs" and render Defendants' Efficacy Representations false and misleading.
 - 73. Antibacterial Resistance. Furthermore, several studies have noted that

BAC may actually increase the incidence of "germs", including because BAC may cause antibacterial resistance in certain microbes.

74. For example, a 2020 publication titled "Effect of sub-lethal chemical disinfection on the biofilm forming ability, resistance to antibiotics and expression of virulence genes of Salmonella Enteritidis biofilm-surviving cells" the authors examined "in food environments" bacteria that "can survive and present increased virulence/resistance." The authors concluded that: "After BAC (Benzalkonium Chloride) and HP (hydrogen peroxide) exposure, biofilm-derived cells presented a down-regulation of rpoS. Exposure to BAC also revealed an up-regulation of invA, avrA and csgD on Salmonella Enteritidis NCTC 13349. The results obtained suggest that biofilm-derived cells that survive disinfection may represent an increased health risk." *See* https://pubmed.ncbi.nlm.nih.gov/31997643/.

2. The Manner of Application Renders the Products Additionally Ineffective

- 75. The concentration and formulation of the Products render them additionally ineffective at killing germs.
- 76. BAC is slow to act against numerous microbes, thus, it must be applied all over and remain on human hands for a substantial period of time in order to kill certain germs.
- 77. Moreover, hand sanitizers are tested in an "optimal environment" that "differs greatly from the real-world setting." *See* The Wall Street Journal, dated December 16, 2009, titled "Kills 99.9% of Germs Under Some Lab Conditions" attached as Exhibit C.
- 78. In one test conducted among eighth graders in Hamilton Ontario, "[t]hree popular sanitizers killed between 46% and 60% of microbes on the students' hands, far short of 99.99%." *Id*.

3. The Products Have a Non-Monograph Status

79. Although this action is brought pursuant to consumer protection and common law based on Defendants' false and misleading label representations, and not

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27 28 based on any FDA regulation, by way of background it should be noted that in 2019 the FDA issued a Final Rule wherein it deferred any regulatory action for three consumer antiseptic rub ingredients, including BAC.

- 80. The FDA deferred making a monograph or nonmonograph finding for these ingredients and stated that the status would be addressed "after completion and analysis of studies to address the safety and effectiveness data gaps of these ingredients or at another time, if these studies are not completed."² Furthermore, the FDA stated that it was deferring a ruling on whether the ingredients, including BAC, are generally recognized as safe and effective ("GRAS/GRAE").
- 81. Accordingly, the Products do not have monograph status, meaning that they are not generally accepted as over-the-counter-drugs and thus are not approved for marketing or labeling under any monograph. Without approval as over-the-counterdrugs and monograph status, there is no generally accepted FDA language for labeling and marketing the Products.

Defendants Falsely Label the Products as "Hypoallergenic" and B. "Gentle"

- 82. Defendants make numerous false and misleading representations about the hypoallergenic and gentle formulation of the Products.
- On the primary display panel, Defendants prominently state that the 83. Products are "Hypoallergenic." In addition, on the back label, Defendants prominently represent next to an image of a doctor, that the Products are "Pediatrician Tested". Defendants also state that the Products are "specially formulated to be tough on dirt and germs, yet gentle on skin" (collectively, the "Skin Safety Representations" and together with the "Efficacy Representations" the "Representations").

² A monograph is described by the FDA as "a kind of 'recipe book' covering acceptable ingredients, doses, formulations, and labeling in over-the-counter drugs.

- 84. Dictionary.com defines hypoallergenic as "designed to reduce or minimize the possibility of an allergic response, as by containing relatively few or no potentially irritating substances."
- 85. Despite the Skin Safety Representations, the Products contain numerous irritating or allergenic ingredients.
- 86. Plaintiff does not claim that she or any member of her family suffered an allergic reaction as a result of using the Products.
- 87. Instead, Plaintiff contends that, had she known that the Products contained known allergens, skin irritants and toxins, she would not have purchased them, or would have paid less for them.
 - 88. **BAC**, the active ingredient in the Products, is an established skin irritant.
- 89. According to a study, which reviewed Mayo Clinic experience from 2000 to 2012 with patch testing, BAC is increasingly associated with allergic contact dermatitis. The study states that from 2001 through 2005 and 2006 through 2010, BAC was among the top 10 most frequent allergens in the standard series.
- 90. A Swiss study found that 5.5% of people with contact dermatitis were sensitized to BAC.
- 91. A study published by the Int J Med Sci., titled "Effect of the Hand Antiseptic Agents Benzalkonium Chloride, Povidone-Iodine, Ethanol, and Chlorhexidine Gluconate on Atopic Dermatitis in NC/Nga Mice," evaluated the effects of BAC on individuals with atopic dermatitis. The study found that, in a clinical setting involving mice, BAC "induced a significant increase in the severity of the clinical score, infiltration of inflammatory cells, local expression of inflammatory cytokines in subcutaneous tissue, and total serum immunoglobulin."
- 92. BAC has also been found to cause adverse health effects, including the triggering of asthma symptoms in people both with and without a history of asthma, and the triggering of respiratory sensitization and asthma that is attributable to hyperresponsiveness and/or inflammation.

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- 93. Based on Defendants' Skin Safety Representations, Plaintiff and reasonable consumers would not expect that the Products' active ingredient would be a top 10 most frequent allergen.
- 94. **Phenoxyethanol** is a known toxin, allergen and a suspected carcinogen. Numerous studies demonstrate that phenoxyethanol can cause DNA mutation in animals.
- 95. The FDA has stated that phenoxyethanol is "a preservative that is primarily used in cosmetics and medications" and that it can "depress the central nervous system and may cause vomiting and diarrhea" in infants.
- In addition, the French Agence Nationale de Securite du Medicament et des 96. *Produits de Sante* has cautioned consumers not to use wipes containing phenoxyethanol on children under the age of three because of health concerns related to "reproductive" and developmental toxicity."
- The Material Safety Data Sheet (MSDS) on phenoxyethanol states that it 97. can cause skin and lung irritation, and that it may also be toxic to the kidneys, nervous system, and liver, and repeated, long-term exposure can cause organ damage. The MSDS further states that the toxic effects can occur through inhalation, skin exposure, and ingestion.
- 98. According to Hazard Notifications from the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), phenoxyethanol presents a category 2 danger for skin irritation, a category 4 danger for acute oral toxicity if swallowed, and a category 2A danger for causing serious eye damage or eye irritation.
- Based on Defendants' Skin Safety Representations, Plaintiff and reasonable 99. consumers would not expect that the Products would contain a toxic and known allergen, particularly where the toxic effects can occur through skin exposure.
- 100. Caprylyl glycol is a synthetic skin conditioning agent, preservative and known irritant.

- 101. *Dihydroxypropyl peg-5 linoleammonium chloride*. According to the PubChem Compound Summary, the GHS information provided by 49 companies demonstrated that the compound does not meet GHS hazard criteria by 36 of the 49 companies. The notifications provided included the warning that the compound causes skin irritation and serious eye irritation.
- 102. *Potassium Sorbate* is a preservative that can cause allergic reactions and skin irritation in skin care products, particularly where it is applied repeatedly or in high concentration.
- 103. *Disodium EDTA*, a chemical preservative, has been found to disrupt the surface of skin cells so that other chemicals may penetrate skin more easily.
- 104. *Fragrance*. According to the FDA, fragrance is a common allergen found in cosmetic products and can cause allergic contact dermatitis.
- 105. Based on Defendants' Skin Safety Representations, Plaintiff and reasonable consumers would not expect that the Products would contain numerous additional known skin irritants.
- 106. If Plaintiff had known that the Skin Safety Representations were false and misleading she would not have purchased the Products or would have purchased them on different terms.

C. Plaintiff Purchased the Products to Her Detriment

- 107. Plaintiff purchased the Products to her detriment.
- 108. Plaintiff purchased the Products multiple times during the class period in various scents, sizes and configurations, including but not limited to Wet Ones travel packs, singles and canisters, and including in or about March of 2020. Plaintiff purchased the Products for personal and family use, including for use on her son. The price paid by Plaintiff was representative of the price paid by similarly situated consumers who purchased the Products. In addition, the Representations on the Products purchased by Plaintiff were the same as the Representations purchased by members of the Class.

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- 109. Plaintiff purchased the Products for the particular purpose of sanitizing hands and killing germs and relied on the Products for this purpose.
- 110. In purchasing the Products, Plaintiff relied on Defendants' Representations, including that the Products "Kill[] 99.99% of Germs" and that they are hypoallergenic and/or gentle on skin.
- 111. Acting reasonably under the circumstances, Plaintiff relied on Defendants' Representations for the truth of the matter stated.
- 112. Had Plaintiff known that Defendants' Representations were false, she would not have purchased the Products or would have purchased them on different terms.
- 113. It is possible, however, that Plaintiff would purchase the Products in the future if the Representations were truthful.

1. Reasonable Consumers Rely on Defendants' Representations

- 114. According to a "senior brand manager of skin care for Playtex Products Inc. [former] maker of Wet Ones antibacterial wipes" "[t]he 99.99% message is more powerful among consumers than 'antibacterial' or 'germ kill' alone " See The Wall Street Journal dated December 16, 2009 attached as Exhibit C.
- 115. On information and belief, Defendants intentionally included the prominent "Kills 99.99% of germs" statement on the front label of the Products to increase sales.
- 116. Furthermore, manufacturers are able to charge a price premium for Products that are labeled as natural or hypoallergenic.
- 117. On information and belief, Defendants intentionally included the Skin Safety Representations, including the prominent "Hypoallergenic" statement on the front label of the Products, in order to increase sales and/or charge a premium for the Products.
- 118. Defendants knew or should have known that reasonable consumers would consider the Representations material in deciding to purchase the Products.

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- 119. Defendants knew or should have known that the Representations could plausibly deceive reasonable consumers into believing that the Products kill 99.99% of germs and/or are hypoallergenic and gentle on skin.
- 120. Reasonable consumers ascribe a common meaning to words on product labels.
 - 121. Reasonable consumes rely on Product labels for their truth and accuracy.
- 122. Reasonable consumers are not required to conduct independent research to determine the truth of label statements.
- 123. Reasonable consumers are not expected to look beyond misleading representations on the front label of a product to determine whether they are false.
- 124. Instead, it is the responsibility of product manufacturers to accurately label their products in a manner that is not misleading.
- 125. Even a perfectly true statement that is couched in a manner that is likely to mislead or deceive consumers is actionable.
- 126. In addition, the failure by a product manufacturer to disclose relevant information is, on its own, actionable.
- 127. In this case, Plaintiff and reasonable consumers reasonably believed that the Product Representations were true.
- 128. Plaintiff and reasonable consumers reasonably believed that the prominent, front panel statement that the Products kill 99.99% of germs was true.
- 129. Plaintiff and reasonable consumers reasonably believed that the prominent, front panel statement that the Products are hypoallergenic was true.
- 130. Plaintiff and reasonable consumers were not required to conduct an independent investigation or to look to any other label information to determine the veracity of Defendants' label statements.
 - 131. As described herein, Defendants' Representations are literally false.
- 132. Accordingly, there is no "common sense" interpretation of the Representations that would overcome their falsity.

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133. The following third-party posts and reviews exemplify consumer reliance and deception based on Defendants' Representations.³

Musthavemom.com Blog Post

- 134. A musthavemom.com post titled "Why I choose Wet Ones Wipes Over Hand Sanitizer" exemplifies consumer reliance on Defendants' label Representations. https://musthavemom.com/why-i-choose-wet-ones-wipes-over-hand-sanitizer/.
- 135. In addition to using the Products based on the belief that the they remove peanut residue from her son's hands, who has a "life threatening" peanut allergy, 4 the poster states: "I am constantly using Wet Ones. I use them after touching surfaces while out and about. Whether I have just come out of the grocery store, or just pumped gas, I use them to remove germs from my hands. After leaving a store I get all my kids in their car seats and they each wash their hands with a Wet Ones Wipe too. After touching carts and who knows what else, I don't want any germs riding home with us on their hands! When we are out and eating at a restaurant I always wash my kids hands with Wet Ones before eating. We use them on play dates, during and after church, shopping, dining, pretty much anywhere we encounter germs!"
- 136. In response to a comment that "Wet ones wipes do not contain alcohol and will not kill Coronavirus!" the poster replies: "As per the label, Wet Ones wipes kill 99.99% of germs. I can't speak specifically to Coronavirus however if they kill 99.99% of germs then I would expect a virus to be included in that." *Id*.
- 137. The must have mom. com post further states: "Wet Ones Antibacterial Hand Wipes are proven to be just as effective as gel hand sanitizers in killing 99.99 percent of

³ Plaintiff is not required to provide evidence in the pleading stage but instead is allowed to set forth her plain factual allegations, for which she will provide support at a later stage of this case. Accordingly, Plaintiff provides this information merely as an example of consumer reliance.

⁴ Whether the wipes are actually effective at removing peanut oil is disputed by a commentator, who also has children with peanut allergies, and says that the wipes cannot safely remove the residue.

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138. The must have mom.com post also states: "Another reason I love Wet Ones Wipes is that they are gentle on skin and are even safe for babies. I don't want to put an alcohol based hand sanitizer on my baby's hands and then watch him put those hands in his mouth. Wet Ones remove the bacteria without the harsh alcohol on his skin or worse, in his mouth. They're hypoallergenic, alcohol- and fragrance-free." Id.

Reviews of the Products from Influenster.com

- 139. Consumers who reviewed the Products on influenster.com also reasonably rely and are misled by Defendants' Representations, including based on the belief that the Products kill 99.99% of germs. See https://www.influenster.com/reviews/wet-onesantibacterial-hand-wipes.
- 140. A review from Dawn S. dated March 28, 2019 states: "Love The convenience of these when we are at the park and need a quick hand cleaning; makes me feel relieved knowing my daughter's hands are well cleaned with these antibacterial wipes that kill 99.99% of germs. I buy these all the time and keep one in the car and 1 in the house. And it cleans hands better than other sanitizers! Wet Ones Antibacterial Hand Wipes" (emphasis added).
- 141. A review from Brenna S. dated February 2, 2018 states: "Absolutely love these wipes. The wipe themselves are nice and soft with a fresh scent. After using them on skin they don't leave a sticky residue to you. Your skin also doesnt get dry nor breaks out from the wipe. Kills 99.99% of germs and takes dirt off easily. Comes in different cute or just regular containers. I definitely recommend these for everyone whether its just fornthe house, road trip, the office, or just to have if your pursue [sic]. Great product!" (Emphasis added).
- 142. A review from Melissa B. dated January 18, 2019 states: "Having a child under 4 these are a must have. I have them in my car, house and purse. I use them for everything, cleaning messes she makes, wiping down things she will touch and

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27 28 **killing any germ that thinks about coming near her!** They smell good and are durable. I'm sure every mother out there has these on hand" (emphasis added).

- 143. A review from Alice P. dated March 20, 2020 states: "#THEBIGCLEAN I picked these up at Target this morning and o y homewith [sic] this virus going around its good to be safe. I use them to wipe my steering wheel, door knobs into my home. Best wipes to protect us from getting sick." (Emphasis added).
- 144. A review from Victoria G. dated March 2, 2017 states: "Loves these! They are perfect for in my daughters diaper bag or on the go to wipe down stuff that sick kids or people have touched I use them everywhere and they get rid of germs I highly recommend them because they are very affective!" (Emphasis added).
- 145. A review from Maria A. dated April 5, 2020 states: "These are nice antibacterial wipes! I'm a #germaphobe so anytime I can sanitize anything, I'm happy. These are perfect for travel, or to keep in the car. It's very affordable. I highly recommend them, especially during this weird time. I'll buy them again. Also, these wipes last awhile!" (Emphasis added).
- 146. A review from Susan B. dated June 4, 2020 states: "I use this relatively inexpensive brand to wipe handles, counters, and other surfaces around the house, especially during this pandemic. In my opinion, this product is practical and effective, and convenient. I will continue to purchase again in the future, and recommend it."

Reviews of the Products from Target.com

- 147. Likewise, reviews of the Products on Target.com demonstrate that reasonable consumers rely on and are misled by Defendants' Representations. See e.g. https://www.target.com/p/wet-ones-antibacterial-hand-wipes-travel-pack-fresh-scent-20ct/-/A-15045578#lnk=sametab.
- 148. A review from Vivid color marker states: "I live in California and we're constantly having issues with COVID-19 spreading I buy antibacterial hand wipes packs and containers every-time I place an order with Target using them everywhere I go. They're easy on my hands and make me safe because when I touch doors, buttons on

my elevator and my car door I pull a wipe sanitize my hands keys and crutches cutting down my exposure to germs significantly "

- 149. A review from Gottattoos1205 states: "Great product! I've bwen [sic] using these for years! It helps a lot cuz I'm in a wheelchair, I can wipe off anything before I touch it, or wipe off me and my chair after! Nice to keep in my purse all the time... even better now during the pandemic!!" *Id*.
- 150. A review from Tgee states: "Always keep these bad boys on me since the pandemic. Very convenient when you are on the road and want to eat something and hand sanitizer doesn't make your hands feel clean. I even use them to wipe surfaces down." *Id*.
- 151. A review from Rabia states: "I love these. I buy them on drive up whenever I can, because in this pandemic, I've been wiping my kids hands down left and right whenever I can. These are convenient, stay really wet until you use them, and I feel like my kids hands are very clean after using. I have already gone through two packs and I know I'll be going through many more." *Id*.

2. Reasonable Consumers Are Deceived by Defendants' Representations

- 152. Reasonable consumers of Defendants' Products believe that the Products are accurately and truthfully labeled and represented, including that they kill 99.99% of germs.
- 153. As demonstrated by posts and reviews of the Products, reasonable consumers are misled and deceived by Defendants' Representations..
- 154. Reasonable consumers of the Products are, for example, misled and deceived into believing that by wiping hands and surfaces with the Products they are effectively disinfecting those hands and surfaces, including by killing 99.99% of germs.
- 155. As stated herein, however, the Products do not kill numerous germs on hands and surfaces, including common and prevalent germs. The Products do not, for example, kill norovirus, HPV, C. diff. and cryptosporidium on hands and surfaces.

- 156. Furthermore, if the active ingredient in the Products does not remain on hands and surfaces for a sufficient amount of time—including based on manner of use, saturation, and evaporation—the Products are substantially or wholly ineffective against numerous germs.
- 157. Reasonable consumers also reasonably rely on the Products to kill coronavirus and are misled and deceived.
- 158. As stated herein, the Products may be ineffective or less effective at killing coronavirus or COVID-19.
- 159. At the time Plaintiff and reasonable consumers purchased the Products, Plaintiff and consumers did not know, and had no reason to know, that the Representations were misleading, deceptive and unlawful. Plaintiff and consumers would not have purchased the Products, or would have purchased them on different terms, if they had known the truth.

3. Defendants Profit from their Misconduct

- 160. According to Defendants' Product labels, the Products are "America's #1 Hand Wipe*".
 - 161. Defendants charge a price premium for their Products.
- 162. On information and belief, Defendants are the #1 selling hand wipe based at least in part on Defendants' label Representations.
- 163. On further information and belief, Defendants are able to charge a price premium for their Products based at least in part on Defendants' label Representations.
- 164. As alleged herein, if reasonable consumers knew about the falsity of Defendants' Representations, they would not purchase the Products or would pay less for them.
- 165. In the last few years, there has been a substantial proliferation in sales of hand hygiene products due to the COVID-19 pandemic.
 - 166. Defendants' sales of the Products greatly increased during this time.

- 167. According to an article from sidneydailynews.com, "[d]ue the increased use of sanitizing wipes amid the pandemic, the [Wet Ones] plant's production began ramping up in January, and then surged in February, going from two shifts working 10 hours a day, four days a week, to nonstop production." *See* https://www.sidneydailynews.com/news/177852/wet-ones-wipes-working-to-meet-demand.
- 168. "Usually you can find (Wet Ones) anywhere, but right now it is very hard to find them. Our demand is sky-high right now. We can not keep up. We almost doubled (in production) from where we were in January . . . (Wet Ones is) a very seasonal product. We could see usual spikes (of consumer consumption) in the flu season, but since COVID happened, we have basically been running 24/7. Since the end of January we haven't stopped production." *Id*.
- 169. As described herein, Defendants' Products are likely less effective against coronavirus than hand sanitizers containing ethyl alcohol as an active ingredient and are certainly less effective than washing hands with soap and water.
- 170. Nevertheless, Defendants profited substantially from the COVID-19 pandemic.
- 171. On information and belief, this profit was due in part to Defendants' false and misleading Representations.

CLASS DEFINITION AND CLASS ALLEGATIONS

- 172. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of herself, on behalf of all others similarly situated, and as a member of the Classes defined as follows (collectively, the "Class"):
 - All citizens of the United States who, within the relevant statute of limitations periods, purchased Defendants' Products ("Nationwide Class");
 - All citizens of California who, within four years prior to the filing of the initial Complaint, purchased Defendants' Products ("California Subclass").

- 173. Excluded from the Class are: (i) Defendants, their assigns, successors, and legal representatives; (ii) any entities in which Defendants have a controlling interest; (iii) federal, state, and/or local governments, including, but not limited to, their departments, agencies, divisions, bureaus, boards, sections, groups, counsels, and/or subdivisions; (iv) all persons presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and (v) any judicial officer presiding over this matter and person within the third degree of consanguinity to such judicial officer.
- 174. Plaintiff reserves the right to amend or otherwise alter the class definition presented to the Court at the appropriate time, or to propose or eliminate sub-classes, in response to facts learned through discovery, legal arguments advanced by Defendants, or otherwise.
- 175. This action is properly maintainable as a class action pursuant to Federal Rule of Civil Procedure 23 for the reasons set forth below.
- 176. <u>Numerosity</u>: Members of the Class are so numerous that joinder of all members is impracticable. Upon information and belief, the Nationwide Class consists of millions of purchasers dispersed throughout the United States, and the California Subclass consists of hundreds of thousands of purchasers throughout the State of California. Accordingly, it would be impracticable to join all members of the Class before the Court.
- 177. <u>Common Questions Predominate:</u> There are numerous and substantial questions of law or fact common to all members of the Class that predominate over any individual issues. Included within the common questions of law or fact are:
 - Whether the Product Representations and omissions are, or any single representation or omission is, false, misleading and/or deceptive;
 - Whether Defendants engaged in unlawful, unfair or deceptive business practices by advertising and selling the Products;
 - Whether Defendants violated California Bus. & Prof. Code § 17200, et seq.; Cal. Bus. & Prof. Code § 17500, et seq.; and/or the Consumers

Legal Remedies Act, Cal. Civ. Code § 1750, et seq.;

- Whether Defendants committed a breach of express warranty;
- Whether Plaintiff and the Class are entitled to equitable and/or injunctive relief;
- Whether Plaintiff and the Class have sustained damage as a result of Defendants' unlawful conduct;
- The proper measure of damages sustained by Plaintiff and the Class; and
- Whether Defendants were unjustly enriched by their unlawful practices.
- 178. **Typicality:** Plaintiff's claims are typical of the claims of the members of the Class she seeks to represent because Plaintiff, like the Class members, purchased Defendants' misbranded Products. Defendants' unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were experienced. Plaintiff and the Class sustained similar injuries arising out of Defendants' conduct. Plaintiff's and Class member's claims arise from the same practices and course of conduct and are based on the same legal theories.
- 179. Adequacy: Plaintiff is an adequate representative of the Class she seeks to represent because her interests do not conflict with the interests of the members of the Class Plaintiff seeks to represent. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel experienced and competent in the prosecution of complex class actions, including complex questions that arise in consumer protection litigation.
- 180. <u>Superiority and Substantial Benefit</u>: A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all members of the Class is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:

- a. The claims presented in this case predominate over any questions of law or fact, if any exists at all, affecting any individual member of the Class;
- b. Absent a Class, the members of the Class will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants profit from and enjoy their ill-gotten gains;
- c. Given the size of individual Class members' claims, few, if any, members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent members have no substantial interest in individually controlling the prosecution of individual actions;
- d. When the liability of Defendants has been adjudicated, claims of all members of the Class can be administered efficiently and/or determined uniformly by the Court; and
- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and members of the Class can seek redress for the harm caused to them by Defendants.
- 181. Because Plaintiff seeks relief for all members of the Class, the prosecution of separate actions by individual members would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendants.
- 182. The prerequisites to maintaining a class action for injunctive or equitable relief pursuant to Fed. R. Civ. P. 23(b)(2) are met as Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or equitable relief with respect to the Class as a whole.
- 183. The prerequisites to maintaining a class action pursuant to Fed. R. Civ. P. 23(b)(3) are also met as questions of law or fact common to Class members predominate

over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

184. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Unfair and Unlawful Business Acts and Practices (Business and Professions Code § 17200, et seq.) (for Plaintiff and the California Subclass)

- 185. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint, as though fully set forth herein.
- 186. Defendants' conduct constitutes an unfair business act and practice pursuant to California Business & Professions Code §§ 17200, *et seq.* (the "UCL"). The UCL provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising"
- 187. Plaintiff brings this claim seeking equitable and injunctive relief to stop Defendants' misconduct, as complained of herein, and to seek restitution of the amounts Defendants acquired through the unfair, unlawful, and fraudulent business practices described herein.
- 188. Defendants' knowing conduct, as alleged herein, constitutes an "unfair" and/or "fraudulent" business practice, as set forth in California Business & Professions Code §§ 17200-17208.
- 189. Defendants' conduct was and continues to be unfair and fraudulent because, directly or through their agents and employees, Defendants made uniform materially false representations and omissions.
- 190. Defendants knowingly and intentionally made the Representations which, as described herein, are false and misleading because the Products do not "kill 99.99%

of germs" and are not hypoallergenic and/or gentle on skin.

- 191. Defendants also made materially false representations and omissions by failing to disclose the truth about the Products, including that the Products do not denature certain microbes and that they contain ingredients that are known irritants and/or allergens.
- 192. Defendants are aware that their Representations and omissions were and continue to be false and misleading.
- 193. Defendants had an improper motive—to derive financial gain at the expense of accuracy or truthfulness—in their practices related to the labeling and advertising of the Products.
- 194. There were reasonable alternatives available to Defendants to further their legitimate business interests, other than the conduct described herein.
- 195. Defendants' misrepresentations of material facts, as set forth herein, also constitute an "unlawful" practice because they violate California Civil Code §§ 1572, 1573, 1709, 1710, 1711, and 1770 and the laws and regulations cited herein, as well as the common law.
- 196. Defendants' conduct in making the Representations and omissions described herein constitutes a knowing failure to adopt policies in accordance with and/or adherence to applicable laws, as set forth herein, all of which are binding upon and burdensome to their competitors. This conduct engenders an unfair competitive advantage for Defendants, thereby constituting an unfair business practice under California Business & Professions Code §§ 17200-17208.
- 197. In addition, Defendants' conduct was, and continues to be, unfair in that their injury to countless purchasers of the Products is substantial, and is not outweighed by any countervailing benefits to consumers or to competitors.
- 198. Moreover, Plaintiff and members of the California Subclass could not have reasonably avoided such injury. Defendants' uniform, material misrepresentations and omissions regarding the Products were likely to deceive, and Defendants knew or should

have known that their misrepresentations and omissions were untrue and misleading. Plaintiff purchased the Products in reliance on the Representations made by Defendants, including that the Product labeling was accurate, and without knowledge of Defendants' misrepresentations and omissions.

- 199. Plaintiff and members of the California Subclass have been directly and proximately injured by Defendants' conduct in ways including, but not limited to, the monies paid to Defendants for the Products, interest lost on those monies, and consumers' unwitting support of a business enterprise that promotes deception and undue greed to the detriment of consumers, such as Plaintiff and California Subclass members.
- 200. As a result of the business acts and practices described above, Plaintiff and members of the California Subclass, pursuant to § 17203, are entitled to an Order enjoining such future wrongful conduct on the part of Defendants and such other Orders and judgments that may be necessary to disgorge Defendants' ill-gotten gains and to restore to any person in interest any money paid for the Products as a result of the wrongful conduct of Defendants.
- 201. Pursuant to Civil Code § 3287(a), Plaintiff and the California Subclass are further entitled to pre-judgment interest as a direct and proximate result of Defendants' unfair and fraudulent business conduct. The amount on which interest is to be calculated is a sum certain and capable of calculation, and Plaintiff and the California Subclass are entitled to interest in an amount according to proof.

SECOND CAUSE OF ACTION Deceptive Advertising Practices (California Business & Professions Code §§ 17500, et seq.)

(for Plaintiff and the California Subclass)

- 202. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint, as though fully set forth herein.
- 203. California Business & Professions Code § 17500 prohibits "unfair, deceptive, untrue or misleading advertising"

- 204. Defendants violated § 17500 when they represented, through their false and misleading Representations and omissions, that Defendants' Products possessed characteristics and value that they did not actually have. Defendants knowingly and intentionally made the Representations which, as described herein, are false and misleading because the Products do not "kill[] 99.99% of germs" and are not hypoallergenic and/or gentle on skin.
- 205. Defendants also made materially false representations and omissions by failing to disclose the truth about the Products, including that the Products do not denature certain microbes and that they contain ingredients that are known irritants and/or allergens.
- 206. Defendants' deceptive practices were designed to induce reasonable consumers like Plaintiff to purchase the Products. Defendants' uniform, material misrepresentations and omissions regarding the Products were likely to deceive, and Defendants knew or should have known that their uniform misrepresentations and omissions were untrue and/or misleading. Plaintiff purchased the Products in reliance on the Representations made by Defendants, including that the Product labeling was accurate, and without knowledge of Defendants' misrepresentations and omissions.
- 207. Plaintiff and members of the California Subclass have been directly and proximately injured by Defendants' conduct in ways including, but not limited to, the monies paid to Defendants for the Products, interest lost on those monies, and consumers' unwitting support of a business enterprise that promotes deception and undue greed to the detriment of consumers, such as Plaintiff and Subclass members.
- 208. The above acts of Defendants were and are likely to deceive reasonable consumers in violation of § 17500.
- 209. In making the statements and omissions alleged herein, Defendants knew or should have known that the statements and representations were untrue or misleading, and acted in violation of § 17500.
 - 210. Defendants continue to engage in unlawful, unfair and deceptive practices

- 211. As a direct and proximate result of Defendants' unlawful conduct in violation of § 17500, Plaintiff and members of the California Subclass, pursuant to § 17535, are entitled to an Order of this Court enjoining such future wrongful conduct on the part of Defendants, and requiring Defendants to disclose the true nature of their misrepresentations and omissions.
- 212. Plaintiff and members of the California Subclass also request an Order requiring Defendants to disgorge their ill-gotten gains and/or award full restitution of all monies wrongfully acquired by Defendants by means of such acts of false advertising, plus interests and attorneys' fees.

THIRD CAUSE OF ACTION Consumer Legal Remedies Act (Cal. Civ. Code § 1750, et seq.) (for Plaintiff and the California Subclass)

- 213. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint, as though fully set forth herein.
- 214. Plaintiff brings this action pursuant to California's Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750, et seq.
- 215. The CLRA provides that "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer are unlawful."
- 216. The Products are "goods," as defined by the CLRA in California Civil Code §1761(a).
- 217. Defendants are a "person," as defined by the CLRA in California Civil Code §1761(c).
- 218. Plaintiff and members of the California Subclass are "consumers," as defined by the CLRA in California Civil Code §1761(d).
- 219. Purchase of the Products by Plaintiff and members of the California Subclass are "transactions," as defined by the CLRA in California Civil Code §1761(e).

- 220. Defendants violated Section 1770(a)(5) by representing that the Products have "characteristics, . . . uses [or] benefits . . . which [they] do not have" in that the Products are falsely and misleadingly labeled and represented, as described herein.
- 221. Similarly, Defendants violated section 1770(a)(7) by representing that the Products "are of a particular standard, quality, or grade . . . if they are of another" by making the Representations and omissions described herein.
- 222. In addition, Defendants violated section 1770(a)(9) by advertising the Products "with intent not to sell them as advertised" in that the Products are misrepresented and misbranded as described herein.
- 223. Defendants' uniform, material, misrepresentations and omissions regarding the Products were likely to deceive, and Defendants knew or should have known that their misrepresentations and omissions were untrue and misleading.
- 224. Plaintiff and members of the California Subclass could not have reasonably avoided injury. Plaintiff and members of the California Subclass were unaware of the existence of facts that Defendants suppressed and failed to disclose and Plaintiff and members of the California Subclass would not have purchased the Products and/or would have purchased them on different terms had they known the truth.
- 225. Plaintiff and members of the California Subclass have been directly and proximately injured by Defendants' conduct. Such injury includes, but is not limited to, the purchase price of the Products and/or the price of the Products at the prices at which they were offered.
- 226. Given that Defendants' conduct violated § 1770(a)(5), Plaintiff and members of the California Subclass are entitled to seek and seek injunctive relief to put an end to Defendants' violations of the CLRA.
- 227. Moreover, Defendants' conduct is malicious, fraudulent, and wanton in that Defendants intentionally misled and withheld material information from consumers to increase the sale of the Products.
 - 228. Pursuant to California Civil Code § 1782(a), on March 18, 2020, Plaintiff

on her own behalf, and on behalf of members of the California Subclass, notified Defendants of the alleged violations of the Consumer Legal Remedies Act by letter setting forth Plaintiff's claims. Despite giving Defendants more than 30-days from the date of the notification letter to provide appropriate relief for violations of the CLRA, Defendants have failed to provide any such relief. As such, Plaintiff also seeks compensatory, monetary and punitive damages, in addition to equitable and injunctive relief, and requests that this Court enter such Orders or judgments as may be necessary to restore to any person in interest any money which may have been acquired by means of such unfair business practices, and for such other relief as is provided in California Civil Code § 1780 and in the Prayer for Relief.

229. Plaintiff further requests pursuant to § 1780(a)(2) that the Court enjoin Defendants from continuing to employ the unlawful methods, acts, and practices alleged herein.

FOURTH CAUSE OF ACTION Breach of Express Warranty

(for Plaintiff, the Nationwide Class, and California Subclass)

- 230. Plaintiff re-alleges and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint, as though fully set forth herein.
- 231. By advertising and selling the Products at issue, Defendants made promises and affirmations of fact on the Products' packaging and labeling, as described herein. This labeling and advertising constitutes express warranties and became part of the basis of the bargain between Plaintiff and members of the Class, and Defendants.
- 232. Defendants, through their advertising and labeling, created express warranties that the Products comport with the Representations. Specifically, Defendants created express warranties that the Products satisfy the Efficacy and Skin Safety Representations, including that the Products kill 99.99% of germs and are hypoallergenic and/or gentle on skin.
 - 233. The express warranties appear on all Product labels and specifically relate

to the goods being sold.

- 234. Despite Defendants' express warranties about the nature of the Products, the Products do not comport with the Representations. Thus, the Products were and are not what Defendants represented them to be.
- 235. Accordingly, Defendants breached express warranties about the Products and their qualities because the Products do not conform to Defendants' affirmations and promises.
- 236. Plaintiff provided Defendants with pre-suit notice of the breach of warranty, including by letter dated March 18, 2020.
 - 237. Plaintiff and members of the Class purchased the Products.
- 238. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and members of the Class were harmed in the amount of the purchase price they paid for the Products. Further, Plaintiff and members of the Class have suffered and continue to suffer economic losses and other general and specific damages including, but not limited to, the amounts paid for the Products, and any interest that would have accrued on those monies, in an amount to be proven at trial.

FIFTH CAUSE OF ACTION QUASI-CONTRACT

(for Plaintiff, the Nationwide Class and California Subclass)

- 239. Plaintiff repeats and re-alleges the allegations of the preceding paragraphs as if fully set forth herein.
- 240. By purchasing the Products, Plaintiff and members of the Class conferred a benefit on Defendants in the form of the purchase price of the Products.
 - 241. Defendants had knowledge of such benefits.
- 242. Defendants appreciated the benefit because, were consumers not to purchase the Products, Defendants would not generate revenue from the sales of the Products.

- 243. Defendants' acceptance and retention of the benefit is inequitable and unjust because the benefit was obtained by Defendants' fraudulent and misleading Representations and omissions and unlawful conduct.
- 244. Equity cannot in good conscience permit Defendants to be economically enriched for such actions at the expense of Plaintiff and members of the Class, and therefore restitution and/or disgorgement of such economic enrichment is required

PRAYER

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, prays for judgment against Defendants as follows:

- A. For an order certifying the Nationwide Class and the California Subclass under Rule 23 of the Federal Rules of Civil Procedure; naming Plaintiff as representative of the Nationwide Class and California Subclass; and naming Plaintiff's attorneys as Class Counsel to represent the Nationwide Class and California Subclass;
- B. For an order declaring that Defendants' conduct violates the statutes and laws referenced herein;
- C. For an order awarding, as appropriate, compensatory and monetary damages, restitution or disgorgement to Plaintiff and the Class for all causes of action;
- D. For an order requiring Defendants to immediately cease and desist from selling their misbranded Products in violation of law; enjoining Defendants from continuing to label, market, advertise, distribute, and sell the Products in the unlawful manner described herein; and ordering Defendants to engage in corrective action;
 - E. For an order awarding attorneys' fees and costs;
 - F. For an order awarding punitive damages;
 - G. For an order awarding pre-and post-judgment interest; and
 - H. For such other and further relief as the Court deems just and proper.

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I. INTRODUCTION

The single salient question on this Motion to Dismiss is whether Plaintiff's Second Amended Complaint satisfies the reasonable consumer standard.\(^1\) The facts alleged plausibly show that Defendants' label representations are literally false and therefore likely to mislead reasonable consumers. Specifically, Plaintiff demonstrates that Defendants' prominent front label statement that Wet Ones hand wipes (the "Products") "kill[] 99.99% of germs" (the "Representation") is false because the Products are substantially ineffective under real-world conditions. Plaintiff shows, for example, that real-world testing of a hand sanitizer with the same active ingredient as the Products killed only 46% of germs when it was tested on the hands of eighth grade students. See Second Amended Complaint, Dkt. No. 63 ("SAC") at ¶ 94. Plaintiff asserts that, under these same real-world conditions, the Products similarly fail to kill the majority of germs from hands. Id. ¶ 95. If the Court accepts as true that under real-world conditions the Products do not kill numerous germs from hands, the SAC plausibly demonstrates that reasonable consumers are likely to be misled by the Representation.

The SAC also demonstrates that the active ingredient in the Products, Benzalkonium Chloride ("BAC"), cannot kill numerous germs, including hundreds of strains of germs that are found on and transmitted by hands. *See e.g.* SAC ¶¶ 52-56 (norovirus is transmitted by hands and there are approximately 25 strains of norovirus that cause on average 19 to 21 million cases of illness per year); ¶¶ 58-61 (many of the more than 100 varieties of HPV are transmitted by hand and cause common warts on the hands of about one-fourth of all people in the United States); ¶ 66 (there are more than

¹ Defendants' instant Motion re-raises each of the arguments made in their previous motions to dismiss, despite the fact that Plaintiff's SAC pleads no new facts that would change the Court's prior analysis on any issue other than the reasonable consumer standard. *See e.g.* Dkt. No. 63-5 (redline comparison of Plaintiff's Second and First Amended Complaints). For the sake of completeness, Plaintiff has addressed each of the issues raised by Defendants below.

190 species of mycobacteria, some of which are transmitted by hand and cause serious infection); ¶¶ 70-71 (numerous types of coronavirus are not killed by BAC); ¶¶ 75-78 (C. difficile is transmitted by hands and causes 15-55% of all diarrheas). The Products cannot kill these germs, which account for millions of cases of infection in the United States each year. *Id.* If the Court accepts as true that BAC cannot kill germs that are found on and transmitted by hands, the SAC plausibly demonstrates that reasonable consumers are likely to be misled by the Representation.

The SAC also demonstrates that Defendants' prominent front-label representation that the Products are "Hypoallergenic" (the "Hypoallergenic Representation" or collectively with the kills 99.99% of germs Representation, the "Representations") is false. The dictionary.com definition of "hypoallergenic" is "designed to reduce or minimize the possibility of an allergic response, as by containing relatively few or no potentially irritating substances." SAC ¶ 101. The Products, however, contain at least seven ingredients that are established skin irritants. SAC ¶¶ 105-110. If the Court accepts as true that reasonable consumers plausibly believe that the Products have few or no potentially irritating substances based on the Hypoallergenic Representation, the SAC demonstrates that reasonable consumers are likely to be misled.

Defendants do not dispute that their Representations are false. Instead, they argue that Plaintiff's interpretation of the Representations is implausible. Defendants' implausibility arguments, however, are not based on common sense but instead on facts that are not before the Court and unfounded assumptions that would require improper, material determinations at the pleading stage. Moreover, Defendants' arguments appear to demonstrate a fundamental misunderstanding of Plaintiff's claims.

Defendants argue, for example, that no reasonable consumer would understand that the Products should be used on surfaces instead of hands. *See* Defendants' Memorandum In Support of Motion to Dismiss Plaintiff's Second Amended Class Action Complaint, Dkt. No. 68-1, ("MTD SAC") at 6-8. Plaintiff's SAC, however, does not contain a single allegation concerning use of the Products on surfaces.

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The majority of Defendants' other implausibility arguments center around the entirely unsupported conclusion that consumers have an understanding of the complex nature of pathogens that cause infection, or how those pathogens are killed. See e.g. MTD SAC at 9:1-4 (Plaintiff "fails to explicitly allege that one can prevent illness from cryptosporidium, toxoplasmosis, or HPV by washing one's hands."); *Id.* at 10:9-10 ("Plaintiff fails to allege that reasonable consumers could expect to protect themselves from [norovirus] outbreaks even using soap and water."); *Id.* at 12:9-14 ("Plaintiff still fails to provide an explanation for why" consumers would use the Products "instead of washing their hands with soap and water after cleaning out cat litter, changing a diaper, caring for an infected person, touching bathroom fixtures, or handling undercooked food."). These arguments completely miss the mark. Plaintiff's SAC does not plead any facts about consumer understanding of germs or how they are or are not killed. Instead, Plaintiff alleges that she and reasonable consumers relied on Defendants' label Representation for its truth. SAC ¶¶ 134-140. Thus, because consumers believe the Representation means that the Products kill 99.99% of germs, they plausibly expect the Products to kill more germs from their hands than the Products in fact kill. This is true irrespective of the specific circumstance of how those germs might occur or how the germs otherwise could be killed. Furthermore, conclusions about consumer knowledge of germs and how they are transmitted and killed are not based on common sense but require findings of material fact, which are improper at this stage of the proceedings.

Defendants' numerous assertions about handwashing and soap and water also require findings of fact that cannot be made at the pleading stage. Defendants' arguments would require the Court to find that consumers view the back label of the Products and form an understanding of the importance of handwashing from that label. These findings would be contrary to the facts pled in the SAC. See SAC ¶¶ 36-39. Alternatively, Defendants' assertions require the Court to determine that consumers have a general understanding of the importance of handwashing, which ameliorates the falsity of the front label Representation. Such a finding is also improper at this stage.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. The SAC Alleges the Products do not Kill 99.99% of Germs on Hands

Plaintiff's SAC contains additional facts showing that Defendants' prominent front label representation that the Products "Kill[] 99.99% of Germs" is literally false, including facts demonstrating that the Products: (1) are ineffective under real-world conditions; and (2) do not kill numerous common germs that are transmitted by hands.

The real-world condition of consumers' hands substantially impacts the overall effectiveness of the Products. Hands that are dirty, greasy or grimy vastly limit the ability of the Products to kill germs. SAC ¶¶ 32-33. Independent testing conducted under real-world conditions on the hands of eighth grade students determined that the hand sanitizer Soapopular, which also contains BAC as the active ingredient but at a higher concentration than is in the Products, killed only 46% of the germs on the students' hands. SAC ¶¶ 93-95. This real-world testing is in sharp contrast to the testing conducted by Defendants, which is performed under "optimal" laboratory conditions. ¶ 92. Furthermore, Plaintiff alleges that Defendants' Products are similarly ineffective or even less effective than the tested Soapopular sanitizer because the Products contain a lower concentration of BAC. SAC ¶ 9.

BAC also cannot kill numerous germs that are transmitted by hand, including common germs. Plaintiff includes information concerning "the limitations of the Products to kill certain microorganisms" in the SAC "to demonstrate the falsity of Defendants' Efficacy Representations. This information is not a comprehensive summary of all of the germs that the Products fail to kill, nor does it describe the overall ineffectiveness of the Products when they are applied to hands." ¶ 44.

The Products do not kill approximately 25 strains of norovirus, which is found on and transmitted by hands. SAC ¶¶ 52-56. The Products do not kill more than 100 varieties of HPV, which is transmitted by hands and causes common warts on the hands and fingers of about 25% of people. SAC ¶¶ 68-61. The Products do not kill C. difficile, which causes between 15-55% of all diarrheas and can be spread to everything that

infected people touch. SAC ¶¶ 75-77. In addition, the Products do not kill numerous other germs that are transmitted by hands. *See e.g.* SAC ¶¶ 82-83 (the pathogen causing toxoplasmosis may be responsible for 40 million infections in the United States and can be transmitted by hands); ¶¶ 84-86 (cryptosporidium can be transmitted by hands); ¶¶ 63-64 (pseudomonas infection can be transmitted by hands); ¶¶ 65-66 (there are more than 190 species of mycobacteria, some of which can be found on and transmitted by hands). In addition, the Products are ineffective at killing certain coronaviruses found on human hands. ¶ 73.

B. The SAC Shows the Products Are Not Hypoallergenic

The SAC also demonstrates the falsity of Defendants' prominent front label Hypoallergenic Representation. "Dictionary.com defines hypoallergenic as 'designed to reduce or minimize the possibility of an allergic response, as by containing relatively few or no potentially irritating substances." SAC ¶ 101. The Products, however, contain numerous irritating and allergenic ingredients, including the active ingredient in the Products, which is a top 10 most frequent allergen. SAC ¶¶ 102, 109.

III. PROCEDURAL HISTORY

Plaintiff filed her original complaint on July 31, 2020. Dkt. No. 1. Defendants filed a motion to dismiss. Dkt. No. 17 ("Original MTD"). On June 7, 2021, the Court granted Defendants' motion to dismiss without prejudice. Dkt. No. 54 ("Original MTD Order"). In its Original MTD Order, the Court found that Plaintiff "has both constitutional and statutory standing." *Id.* at 5. The Court also found that Plaintiff satisfied the Rule 9(b) standard (*id.* at 7-8); and that there was no primary jurisdiction or preemption of Plaintiff's claims (*id.* at 12-17). The Court granted the Original MTD based on the finding that Plaintiff did not meet her burden to satisfy the reasonable consumer standard. *Id.* at 8-11.

Plaintiff filed her First Amended Complaint on July 7, 2021. Dkt. No. 55 ("FAC"). Defendants moved to dismiss the FAC. Dkt. No. 58 ("MTD FAC"). On February 16, 2022, the Court granted Defendants' MTD FAC. Dkt. No. 62

("MTD FAC Order"). The Court again found that Plaintiff had constitutional and statutory standing. *Id.* at 7-11. The Court also found that Plaintiff properly sought an equitable remedy. *Id.* at 23-24. The Court granted the MTD FAC based on the finding that Plaintiff failed to satisfy the reasonable consumer standard. *Id.* at 12-21. Plaintiff timely filed her SAC, which gives rise to the instant Motion to Dismiss. Dkt. No. 68.

IV. LEGAL STANDARD

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A complaint must include factual allegations that are specific enough "to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). This does not "require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *See* MTD FAC Order at 5:26-28 (citing cases).

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a complaint. *See Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). The court must accept as true all "well-pleaded factual allegations". *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). The court construes all material allegations in the light most favorable to the nonmoving party. *Cedars-Sinai Med. Ctr. v. Nat'l League of Postmasters of U.S.*, 497 F.3d 972, 975 (9th Cir. 2007).

Under Rule 12(b)(1), "The district court resolves a facial attack as it would a motion to dismiss under Rule 12(b)(6): Accepting the plaintiff's allegations as true and drawing all reasonable inferences in the plaintiff's favor, the court determines whether the allegations are sufficient as a legal matter to invoke the court's jurisdiction." *Leite v. Crane Co.*, 749 F.3d 1117, 1121 (9th Cir. 2014) (citation omitted).

V. PLAINTIFF SATISFIES THE REASONABLE CONSUMER STANDARD

Plaintiff's claims under California's consumer protection laws are examined under the lens of the reasonable consumer standard and whether "members of the public are likely to be deceived." *Williams v. Gerber Prod. Co.*, 552 F.3d 934, 938 (9th Cir.

2008) (citations omitted). The Court considers whether the Representations are misleading from the point of view of an "ordinary consumer acting reasonably under the circumstances" who "is not versed in the art of inspecting and judging a product." *Colgan v. Leatherman Tool Grp., Inc.*, 135 Cal. App. 4th 663, 682 (2006) (internal quotation marks omitted); *see also Moore v. Mars Petcare US, Inc.*, 966 F.3d 1007, 1017-18 (9th Cir. 2020). Such a consumer need be neither "exceptionally acute and sophisticated" nor "wary or suspicious." *Lavie v. Procter & Gamble Co.*, 105 Cal. App. 4th 496, 509-10, 512 (2003).

Under this standard, whether a reasonable consumer is likely to be misled is usually a factual question that cannot be resolved on a motion to dismiss. *Williams*, 552 F.3d at 938; *see also Colucci v. ZonePerfect Nutrition Co.*, No. 12-2907-SC, 2012 WL 6737800, at *7 (N.D. Cal. Dec. 28, 2012) (whether a "reasonable consumer is likely [to] be deceived by the labeling of [defendant's] nutrition bars" is "as the Ninth Circuit and numerous courts have held, [an] issue [] generally not amenable to resolution on the pleadings because it involves issues of fact."); *Khasin v. Hershey Co.*, No. 5:12-CV-01862 EJD, 2012 WL 5471153, at *7 (N.D. Cal. Nov. 9, 2012) ("the issues Defendant raise[s] ultimately involve questions of fact as to whether Plaintiff was or was not deceived by the labeling; this argument is therefore beyond the scope of this Rule 12(b)(6) motion").²

There are three general exceptions to the rule that the reasonable consumer question cannot be answered at the pleading stage, none of which apply here. *See e.g.*

² See also Sebastian v. Kimberly-Clark Corp., No. 17-CV-442-WQH-JMA, 2017 WL 6497675, at *5 (S.D. Cal. Dec. 18, 2017) ("The Court concludes that this is not the rare situation where granting a motion to dismiss Plaintiff's claims regarding deceptive advertising is appropriate Plaintiffs have alleged sufficient facts to support an inference that a reasonable consumer would be deceived by the advertising and packaging of [the] products."); Hunter v. Nature's Way Prod., LLC, No. 16-CV-532-

WQH-BLM, 2016 WL 4262188, at *7 (S.D. Cal. Aug. 12, 2016), on reconsideration, No. 16-CV-0532-WQH-AGS, 2018 WL 340233 (S.D. Cal. Jan. 9, 2018).

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Brady v. Bayer Corp., 26 Cal. App. 5th 1156, 1165-66 (2018) (describing the "rare" situations where a mislabeling case may be subject to early dismissal, where: (i) a claim runs contrary to common sense; (ii) a claim is literally true; and (iii) a product has a sufficiently prominent qualifier on the front of the product). These exceptions are inapplicable because Defendants' Representations are literally false and there is no prominent, front label qualifier.

A. <u>Plaintiff Plausibly Alleges that the Products Do Not Kill 99.99% of Germs on</u> Hands

As described in Section II.A. *supra*, Plaintiff's SAC contains detailed allegations that Defendants' prominent front label Representation that the Products kill 99.99% of germs is false because "the Products do not 'kill' 99.99% of the organisms that cause disease from the hands of consumers." SAC ¶ 5. Plaintiff alleges that, in a real-world setting when they are applied to human hands, the Products kill far fewer than 99.99% of germs. SAC ¶¶ 8-9, 93-95 (describing a real-world study conducted on Soapopular brand hand sanitizer, which contains BAC at a greater concentration than Defendants' Products and found that the sanitizer killed only 46% of germs on hands). Plaintiff also describes numerous "germs" that are found on and transmitted by hands, many of which are common germs, that the Products simply cannot kill. See e.g. SAC ¶¶ 45-87 (describing why BAC cannot kill numerous germs found on and transmitted by hands, including germs that cause millions of cases of infection in the United States annually). Furthermore, and contrary to Defendants' assertion that the independent testing referenced by Plaintiff does not pertain to the wipes at issue, Plaintiff plausibly asserts that, because the Products contain a lower concentration of BAC, they "would be similarly ineffective or even less effective at killing germs on hands" as the Soapopular brand hand sanitizer. SAC ¶ 95.3

³ At a later stage, Plaintiff will prove with discovery and scientific evidence the ineffectiveness of the Products. At this stage, however, the well-pled facts must be accepted as true, and Defendants' unsupported statement that "rubbing the wipes on

Plaintiff's allegations of literal falsity satisfy the reasonable consumer standard at the pleading stage. Moore, 966 F.3d at 1017-1019; Williams, 552 F.3d at 939; Ham v. Hain Celestial Grp., Inc., 70 F. Supp. 3d 1188, 1194 (N.D. Cal. 2014); Brady, 26 Cal. App. 5th at 1167 ("[T]here is no protection for literal falseness."); see also Mier v. CVS Pharmacy, Inc., No. SACV2001979DOCADS, 2021 WL 1559367, at *6 (C.D. Cal. Mar. 22, 2021) ("[T]he Court determines that Plaintiff has stated a plausible claim that a reasonable consumer would be deceived by CVS's [hand sanitizer] labeling."); Macormic v. Vi-Jon, LLC, No. 4:20-CV-1267-HEA, 2021 WL 6119166 at *6 (E.D. Mo. Aug. 6, 2021) ("Plaintiffs' factual allegations plausibly show that a reasonable customer would believe the Products kill more germs than they actually do.").

1. Defendants' "Implausibility" Arguments Contradict the Facts Pled and Prematurely Would Require Numerous Findings of Material Fact

Accepting the well-pled facts as true, it is plain that the Representations are false on their face and that reasonable consumers are likely to be misled. Under the *Brady* test, Defendants would have to demonstrate that Plaintiff's allegations "run contrary to common sense." Each of Defendants' "implausibility" arguments, however, is not based on common sense but instead is grounded in complex facts that are not before the Court, or unsupported assumptions that would require findings of material fact, which would contravene the facts pled in the SAC.

a. Defendants' false and irrelevant "facts" should be disregarded

Defendants make numerous false or irrelevant assertions in their MTD SAC, which should be disregarded. Contrary to Defendants' incorrect and repeated assertion, there are no allegations in Plaintiff's SAC regarding the use of the Products on surfaces. *See e.g.* MTD SAC at 7-8. Accordingly, whether the Products are or are not understood

hands further cleans them of excess dirt and germs" should be disregarded. *See* MTD SAC at 13:24-27.

⁴ At a later stage, Plaintiff will submit evidence showing that consumers are in fact misled and deceived by the Representations.

by consumers to be surface wipes or are effective as such is not presently before the Court. *Id.* In addition, there are no facts showing that Plaintiff or reasonable consumers are misusing the Products. MTD SAC at 13. Instead, Plaintiff alleges that the "concentration and formulation" of the Products reduces their efficacy. SAC ¶ 90. Plaintiff also alleges that the condition of the hands to which the Products are applied reduces their efficacy. SAC ¶ 33.

Plaintiff is not required at the pleading stage to anticipate and refute defenses that Defendants may raise at a later stage, which require fact discovery to address. Plaintiff is not required to "explicitly state that one can prevent illness from cryptosporidium, toxoplasmosis, or HPV by washing one's hands" (MTD SAC at 9:3-4) or "allege that reasonable consumers would expect to protect themselves from such outbreaks [of norovirus] even using soap and water." MTD SAC at 10:9-10. Moreover, there are no "common sense" facts before the Court related to Defendants' assertions. Instead, and as described below, Defendants' arguments would involve findings of material facts related to consumer knowledge of germs. In addition, Defendants' arguments are contrary to Plaintiff's allegations showing that Defendants' Representations are false on their face. See e.g. SAC ¶ 27-33; 131-139; see also SAC ¶ 38 (as described below, whether consumers view the back label of the Products has not been established, however, Defendants' statement on that label that the Products "provid[e] a better clean than hand sanitizers" would reinforce the false notion that that they kill 99.99% of germs on hands).

Defendants' argument about norovirus demonstrates the depth of Defendants' misunderstanding of Plaintiff's claims. *See* MTD SAC at 10 (arguing that consumers do not expect hand wipes to protect them from contaminated ready-to-eat foods or, alternatively, that food workers do not purchase the Products for personal use and therefore Plaintiff's CLRA claim would not apply). The information in the SAC showing that norovirus outbreaks are linked to food-service settings simply shows that the virus is, in fact, spread by hands. SAC ¶¶ 54-55 (infected workers spread the virus to the foods

they touch). Plaintiff's claims, however, are not limited to a food service setting. *See e.g.* SAC ¶ 52 (citing the CDC page on norovirus, which states "Most outbreaks of norovirus illness happen when infected people spread the virus to others through direct contact, such as by caring for them or sharing food or eating utensils with them."; "Norovirus outbreaks on school and university campuses have even led to campus closures. Close quarters, shared spaces, and high-touch surfaces make it easy for norovirus to spread in schools." https://www.cdc.gov/norovirus/trends-outbreaks/outbreaks.html). Accordingly, anytime consumers use the Products after touching something infected with norovirus, the virus is not killed from their hands.

Furthermore, the essential point of Plaintiff's claims is not that food-workers may spread the virus to the food or food service items that they touch with their bare hands. Instead, the critical fact is that consumers, who eat in restaurants or other food service settings, use the Products on their hands prior to consuming food based on the false belief that the Products kill 99.99% of germs on their hands. In reality, however, the Products—in any setting—are simply not able kill norovirus, including for example, if a consumer touches a food service item or utensil that is contaminated with the virus. Thus, reasonable consumers use the Products prior to consuming food at restaurants but, as Defendants admit, the Products do not in fact protect consumers from norovirus. *See* MTD SAC at 10:14-15 (in food service settings, the wipes would not protect consumers from contaminated food). Accordingly, consumers purchase and use the Products based on the Representation, and are misled and deceived because the Products do not kill germs that consumers reasonably expect them to eliminate.

b. Defendants' hand washing arguments require findings of fact

The vast majority of Defendants' implausibility arguments are based on unfounded assertions about consumer understanding of hand washing or use of soap and water. *See e.g.* MTD SAC at 11:2; 11:11-12; 12:12-14; 12:19-20. These arguments would require that the Court make improper findings of material fact at the pleading stage that contradict the facts pled in the SAC. Accordingly, Defendants' arguments are

not based on "common sense" but instead would require discovery and complex analysis of consumer behavior. Rather than put the proverbial cart before the horse, the Court should accept Plaintiff's well-pled facts in the SAC regarding consumer deception as true and disregard Defendants' unfounded conjecture.

Defendants' false and premature assumptions can be grouped as follows:

First, Defendants' arguments assume that consumers read the statement on the back label of the Products at the time of purchase, which is the only place hand washing could even be construed to be mentioned on the Products. SAC ¶ 35 (The Back Panel Statement says in part "They are specially formulated to be tough on dirt and germs, yet gentle on skin, so you can confidently keep your hands fresh and clean when soap and water are not available."). Whether consumers in fact view the back label at the time of purchase requires a finding of fact that is reserved for future discovery. At this stage, Plaintiff's allegation that "numerous consumers of Defendants' Products do not view the Back Panel Statement at the time of purchase" is accepted as true. SAC ¶ 36.

Second, assuming *arguendo* that consumers do view the back label of the Products at the time of purchase, Defendants' arguments assume that the Back Panel Statement gives rise to an understanding of the importance of hand washing that would ameliorate consumer deception based on the front label Representation. This assumption is contrary to the facts pled and the prior findings of the Court. *See e.g.* SAC ¶¶ 37-39 (the Back Panel Statement is additionally false and misleading); MTD FAC Order at 15:10-16 ("The Court disagrees with the significance Defendants ascribe to that statement. Just by referencing that Wet Ones may be used to keep hands fresh and clean when soap and water are not available does not mean that a reasonable consumer would assume that Wet Ones do not kill germs as effectively as washing one's hands.").

Furthermore, the meaning ascribed to the back label statements is an issue of material fact that is reserved for discovery and expert analysis. *See Williams*, 552 F.3d at 939; *Mier*, 2021 WL 1559367, at *5 ("Whether this qualification on the back label clears up a consumer's potential confusion that the Product kills 99.99% of germs is a

question of fact not appropriate for the pleadings stage."); *Bush v. Rust-Oleum Corp.*, No. 20-CV-03268-LB, 2021 WL 24842, at *5 (N.D. Cal. Jan. 4, 2021) ("The court cannot conclude as a matter of law that the [back label] disclosure is 'clear and prominent qualifying language' that qualifies the front-label claims and prevents deception"); *Brady*, 26 Cal. App. 5th at 1172 ("You cannot take away in the back fine print what you gave on the front in large conspicuous print."). At this stage, Defendants' unfounded speculation concerning the back label is disregarded and Plaintiff's plausible allegations that the Back Panel Statement is additionally false and misleading are accepted as true.

Third, even if Defendants were not intending to reference the Back Panel Statement in their MTD SAC, their arguments prematurely assume that consumers have an inherent understanding of complex scientific issues, including (i) how germs are transmitted, (ii) how germs are killed, and (iii) the importance of hand washing or hand hygiene. None of these material facts have been pled or otherwise established.

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⁵ This case is distinct from those situations where a manufacturer includes legible clarifying language on the front label of a product. For example, in Ebner v. Fresh, Inc., 838 F.3d 958, 965-66 (9th Cir. 2016), the Court found that "[i]t is undisputed that the Sugar label discloses the correct weight of included lip product." See also e.g. Freeman v. Time, Inc., 68 F.3d 285, 289 (9th Cir. 1995) ("The promotions expressly and repeatedly state the conditions which must be met in order to win. None of the qualifying language is hidden or unreadably small. The qualifying language appears immediately next to the representations it qualifies . . ."); Sponchiado v. Apple Inc., No. 18-CV-07533-HSG, 2019 WL 6117482, at *4 (N.D. Cal. Nov. 18, 2019) ("Accordingly, a reasonable consumer could not be deceived by the iPhone Products' screen size representation, given the qualifying language expressly notifying the consumer that the actual screen area is less than indicated."); Dinan v. SanDisk LLC, No. 18-CV-05420-BLF, 2020 WL 364277, at *9 (N.D. Cal. Jan. 22, 2020), aff'd, 844 F. App'x 978 (9th Cir. 2021) (finding that the term GB was not on its face deceptive); Doniel Elbaz v. Vitals Int'l Grp. et al., No. 8:17-CV-01673-JLS-DFM, 2018 WL 5868739, at *3 (C.D. Cal. Apr. 10, 2018) ("100% Natural' is followed immediately by the qualifier 'Preservative System,' indicating that '100% Natural' applies to only the Shampoo's preservative ingredients. A consumer would have to ignore half of the representation in order to conclude that '100% Natural' applies to the Shampoo as a whole"). Here, Plaintiff alleges "[e]ven if consumers did view the Back Panel Statement, the Statement is additionally false and misleading." SAC ¶ 37.

Defendants' argument regarding C. difficile is illustrative of their improper attempt to substitute their own speculative, material facts for the allegations in the SAC. Defendants state, for example: "It is implausible 'that a *significant portion* of the general consuming public . . . acting reasonably in the circumstances' would not have soap and water available after going to the bathroom . . . It is further implausible that they would instead use a hand wipe labeled for use 'when soap and water are not available'" (MTD at 11:10-14) (emphasis in original). Defendants' claim assumes that C. diff is only spread after using the bathroom, which is contrary to the facts pled. See SAC ¶ 77 (Furthermore, "when someone else touches the . . . surfaces that person touched, they can pick up the germs on their hands."); see also ¶ 77 (citing the CDC article, which states that C. diff is also spread by touching an infected person's skin). Furthermore, Defendants' statement assumes that a reasonable consumer views the back label of the Products, which has not been established. Moreover, Defendants assume that—even if a consumer did read the Back Panel Statement—they would form a specific belief about hand washing based on that statement, which would ameliorate the false front label Representation. These assumptions all require findings of material fact, which have not been made.

Accepting the facts pled as true demonstrates that Defendants' kills 99.99% of germs Representation is false on its face and that reasonable consumers are likely to be misled by that Representation.

B. Plaintiff Plausibly Demonstrates that the Products are not Hypoallergenic

For the reasons stated in Plaintiff's Opposition to Defendants' MTD FAC, Defendants' prominent "Hypoallergenic" representation is false and likely to mislead reasonable consumers. Plaintiff will briefly summarize her arguments here.

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Each of the ingredients described in the SAC is a skin irritant. See SAC ¶¶ 105-118. Furthermore, Plaintiff does not allege that a reasonable consumer would interpret the Products as posing no risk of skin irritation, instead she alleges that "Plaintiff and reasonable consumers would not expect that the Products would contain numerous additional known skin irritants." SAC ¶ 118. These facts are sufficient to demonstrate that reasonable consumers are misled, including by purchasing or paying a price premium for the Products. SAC ¶ 119. See also Kellman v. Whole Foods Mkt., Inc., 313 F. Supp. 3d 1031, 1050-51 (N.D. Cal. 2018); Sebastian v. Kimberly-Clark Corp., No. 17CV442-WQH-JMA, 2017 WL 6497675, at *5 (S.D. Cal. Dec. 18, 2017) (finding the plaintiff alleged sufficient facts to support an inference that reasonable consumer would be deceived by the labels of Huggies Natural Care Baby Wipes products, which contained the words natural, gentle and hypoallergenic but contained synthetic and potentially harmful ingredients).

Rugg v. Johnson & Johnson, cited by Defendants, is distinct because in that case the plaintiffs interposed a fanciful definition of "hypoallergenic" that was not based on an ordinary or dictionary definition. Rugg v. Johnson & Johnson, No. 17-CV-05010-BLF, 2018 WL 3023493, at *2 (N.D. Cal. June 18, 2018) (the plaintiffs asserted that hypoallergenic means that a product "does not contain any skin sensitizers" and "contains no ingredients known to produce a negative reaction—skin irritation, skin corrosion, eye damage, birth defects, cancer, genetic mutations, etc."). The Rugg court, however, cited to several dictionary definitions of the term "hypoallergenic" as examples of potential consumer understanding of that term. See id. at *3 (based on the dictionary definitions, the plaintiffs' assertion of consumer understanding was implausible).

Consistent with the *Rugg* court's analysis supporting the use of dictionary definitions, here, Plaintiff alleges that the dictionary.com definition of "hypoallergenic"

⁶ For the sake of completeness, certain of the ingredients are also described as toxins or having negative health effects, however, this does not negate the fact that the ingredients are also skin irritants.

demonstrates that Defendants' Hypoallergenic Representation is false and misleading. See SAC ¶ 101 (dictionary.com defines hypoallergenic as "designed to reduce or minimize the possibility of an allergic response, as by containing relatively few or no potentially irritating substances."). In addition, Plaintiff's definition of "hypoallergenic" and allegations regarding how she and reasonable consumers understand that term is also wholly consistent with the Court's determination in Kellman. See Kellman v. Whole Foods Mkt., Inc., 313 F. Supp. 3d 1031, 1049-51 (N.D. Cal. 2018) (The plaintiffs are not alleging that a product must contain no skin sensitizers or never cause an allergic response to be hypoallergenic. They are alleging that the defendants' products contain a sufficiently high concentration of skin sensitizers that they may cause sensitization reactions in a substantial number of people."). Accordingly, it is reasonable that Plaintiff and reasonable consumers were misled by Defendants' Hypoallergenic Representation.

VI. DEFENDANTS' BREACH OF WARRANTY AND QUASI-CONTRACT ARGUMENTS ARE MERITLESS

Defendants' arguments that the Court should dismiss Plaintiff's breach of warranty and quasi-contract claims are premised on Defendants' incorrect assumption that their label statements are not false or misleading. Because Plaintiff has plausibly alleged that Defendants' Representations are false, Plaintiff states a claim for breach of warranty. *Brown v. Hain Celestial Grp., Inc.*, 913 F.Supp.2d 881, 899-900 (N.D. Cal. 2012); *Peterson v. CJ Am., Inc,* No. 14-CV-2570- DMS-(JLB), 2015 WL 11582832, at *7 (S.D. Cal. May 18, 2015) ("The statements describing the Annie Chun's products as 'NO MSG ADDED' are sufficiently "specific and unequivocal" to state a claim for breach of express warranty."); *In re Ferrero Litig.*, 794 F. Supp. 2d 1107, 1118 (S.D. Cal. 2011) (finding the plaintiff stated a claim for breach of express warranty where the challenged statements appeared on Nutella's advertising and packaging); *Sebastian*, 2017 WL 6497675, at *5-8 (holding that the "Plaintiffs' allegations regarding Defendant's use of the terms 'natural,' 'gentle,' and 'hypoallergenic' are sufficient to demonstrate that Defendants made 'affirmations of fact or promises or provided a

description of its goods" and that the plaintiff asserted a claim for breach of express warranty); *Kellman*, 313 F.Supp.3d 1031, 1052 (the plaintiff "plausibly alleges that the defendants' labeling of their products as 'hypoallergenic' constituted an affirmation of fact or promise or a description of the goods as being hypoallergenic, that the statement was part of the basis of the bargain, and that the defendants breached their warranty because their products were in fact not hypoallergenic.").

Likewise, because Plaintiff alleges that Defendants' Representations were false, and that Defendants defrauded consumers via the false Representations, she states a claim for quasi contract. *See e.g. Astiana v. Hain Celestial Grp., Inc.,* 783 F.3d 753, 762 (9th Cir. 2015); *Sebastian*, 2017 WL 6497675, at *10.

VII. PLAINTIFF HAS ARTICLE III STANDING

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Despite the Court's findings on two occasions that Plaintiff has Article III standing, Defendants again claim that she does not. There are no new facts pled in the SAC that would alter the Court's prior analysis:

Plaintiff's allegations suffice. Plaintiff alleges that Wet Ones has skinirritating ingredients and that a consumer could contract germs that they would expect Wet Ones to eliminate, rendering Wet Ones' Efficacy and Skin Safety Representations false. Plaintiff further claims that she would not have bought the hand wipes or would have bought them on different terms if she had known the truth This Court is bound to follow this well-established precedent and finds that Plaintiff adequately has alleged an economic injury-in-fact.

See MTD FAC Order, Dkt. No. 62 at 8-9. See also Original MTD Order, Dkt. No. 54 at 5-7 ("Plaintiff has both constitutional and statutory standing. First, Plaintiff alleges an economic harm, or in other words, the loss of money. Plaintiff claims that she would not have bought the hand wipes or would have bought them on different terms if she had known the truth about their efficacy Second, Plaintiff alleges reliance.").

Defendants' improper attempt to tether Article III standing to a merits-based inquiry regarding whether reasonable consumers are deceived by Defendants' Representations contravenes basic Article III jurisprudence. *See e.g.* MTD at 19:14-16

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(arguing that Plaintiff lacks standing because her injury is speculative since "a significant portion of the general consuming public would not be misled by Plaintiff's theory of deception . . ."). Article III standing is personal to Plaintiff, thus, only Plaintiff must show injury at the pleading stage. See Spokeo, Inc. v. Robins, 578 U.S. 330, 338, 136 S. Ct. 1540, 1547, 194 L. Ed. 2d 635 (2016), as revised (May 24, 2016) ("The plaintiff" must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.") (emphasis added; citations omitted). Moreover, the Article III standing inquiry at the pleading stage is distinct from any merits analysis. Maya v. Centex Corp., 658 F.3d 1060, 1068 (9th Cir. 2011) ("But the threshold question of whether plaintiff has standing (and the court has jurisdiction) is distinct from the merits of his claim. Rather, '[t]he jurisdictional question of standing precedes, and does not require, analysis of the merits.") (citing cases). Furthermore, only Plaintiff, as a representative of the putative Class, needs to establish standing at this stage of the case. See e.g. Astiana v. Kashi Co., 291 F.R.D. 493, 500 (S.D. Cal. 2013) (finding the class representative had standing where she "contends that she was induced to purchase Defendant's products at least in part because of Defendant's representations, and that otherwise she would have paid less or purchased other products.").

As the Court previously determined, Plaintiff's allegations that she spent money to purchase the Products, which she would not have spent or would have purchased on different terms, establishes Article III standing. See MTD FAC Order at 8 (finding Plaintiff satisfies the economic injury-in-fact requirement "based on a misrepresentation that led the plaintiff to buy the product."); see also Moore v. Mars Petcare US, Inc., 966 F.3d 1007, 1020 (9th Cir. 2020) ("A consumer who relies on a product label and challenges a misrepresentation contained therein can satisfy the standing requirement of [the UCL] by alleging ... that he or she would not have bought the product but for the misrepresentation.") (citations omitted); Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 327 (2011) ("At this stage, these plaintiffs need only allege economic injury arising

from reliance on [defendant's] misrepresentations Simply stated: labels matter."); *Sebastian v. ONE Brands LLC*, No. 3:20-CV-00009-L-MDD, 2020 WL 5500224, at *2 (S.D. Cal. Sept. 10, 2020) (Plaintiff had standing where she relied on the product labels and purchased the products to her detriment).

A. Plaintiff Adequately Pleads Economic Injury

Defendants are once again also incorrect that Plaintiff fails to allege that she paid a premium for the Products. MTD SAC at 20-22. As the Court previously found, Plaintiff alleges that Defendants made literally false label Representations that induced Plaintiff to purchase Products that she otherwise would not have purchased and "therefore satisfy the requirement of standing." MTD FAC Order at 9-12.

Defendants' own authority, which they cite in support of the false notion that Plaintiff has failed to show a loss of the benefit of the bargain, stands for the exact opposite proposition and demonstrates economic loss: "[o]verpaying for goods or purchasing goods a person otherwise would not have purchased based on alleged misrepresentations by the manufacturer would satisfy the injury-in-fact and causation requirements for Article III standing." *See Estrada v. Johnson & Johnson*, No. 2:14-CV-01051-TLN, 2015 WL 1440466, at *3 (E.D. Cal. Mar. 27, 2015) (citing *Pirozzi v. Apple Inc.*, 913 F. Supp. 2d 840, 846-47 (N.D. Cal. 2012)). *See also Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 965-66 (9th Cir.) ("Under California law, the economic injury of paying a premium for a falsely advertised product is sufficient harm to maintain a cause of action . . . Thus, a consumer's allegation that 'she would not have bought the

⁷ Furthermore, *Estrada* is factually distinct because it is based on the lack of any misleading label statements. *See id.* at *4 ("Plaintiff fails to identify any specific statements about safety made by Defendants that she found material to her decision to purchase the Baby Powder. Instead, Plaintiff continuously cites to the fact that she relied on the label of the Baby Powder when she purchased the product and *her belief* that the product was safe."). Here, by contrast, Plaintiff alleges that Defendants' Representations are literally false and that, had she known the truth, she would have paid less for the Products or would not have purchased them at all.

product but for the misrepresentation ... is sufficient to allege causation ... [and] to allege economic injury."); *Kwikset Corp.*, 51 Cal. 4th at 334 ("in the eyes of the law, a buyer forced to pay more than he or she would have is harmed at the moment of purchase, and further inquiry into such subsequent transactions, actual or hypothesized, ordinarily is unnecessary.").

In addition, contrary to Defendants' assertions, there is no requirement in this Circuit that Plaintiff establish the existence of a competitor product sold at a lessor price or that she considered an alternative product at the time of purchase. MTD SAC at 21-22. Reading these requirements into the standing requirement would contravene the basic purpose of California's consumer protection laws. See Astiana, 291 F.R.D. at 504 ("The UCL and false advertising law are both intended to preserve fair competition and protect consumers from market distortions,' meaning that 'in the eyes of the law, a buyer forced to pay more than he or she would have is harmed at the moment of purchase.") (citing Kwikset, 51 Cal.4th at 334). Robles v. Gojo Industries, Inc., cited by Defendants, actually supports a finding of Article III standing because the Robles court found standing. See Dkt. No. 68-3, at p. 5 of the order. In addition, Robles is distinct because in that case the plaintiff alleged that she chose to purchase Purell hand sanitizer instead of a cheaper alternative based on the label statements. *Id.* Thus, the *Robles* plaintiff put the existence of competing products squarely at issue. Here, Plaintiff alleges that she would not have purchased the Products at all or would have paid less for them had she known the truth, without reference to any other product.

B. Plaintiff Establishes Reliance

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In addition, contrary to Defendants' argument (MTD SAC 25-26), Plaintiff demonstrates that she reasonably relied on Defendants' label Representations. SAC ¶¶ 122-124 ("In purchasing the Products, Plaintiff relied on Defendants' Representations, including that the Products 'Kill[] 99.99% of Germs' and that they are 'Hypoallergenic'. Plaintiff reasonably believed the Products would kill 99.99% of germs from hands and

are hypoallergenic."). Plaintiff's allegations satisfy the standing requirement. See Moore, 966 F.3d at 1020 ("A consumer who relies on a product label and challenges a misrepresentation contained therein can satisfy the standing requirement of [the UCL] by alleging ... that he or she would not have bought the product but for the misrepresentation.") (citations omitted); Kwikset Corp., 51 Cal. 4th at 327 ("At this stage, these plaintiffs need only allege economic injury arising from reliance on [defendant's] misrepresentations Simply stated: labels matter."); Sebastian v. ONE Brands LLC, 2020 WL 5500224, at *2 (Plaintiff had standing where she relied on the product labels and purchased the products to her detriment); Astiana, 291 F.R.D. at 500 (finding the class representative had standing where she "contends that she was induced to purchase Defendant's products at least in part because of Defendant's representations, and that otherwise she would have paid less or purchased other products.").

"Moreover, at the motion to dismiss stage, 'actual reliance ... is inferred from the misrepresentation of a material fact.' Whether a misrepresentation is sufficiently material to allow for an inference of reliance is generally a question of fact that cannot be decided at the motion to dismiss stage." *Moore*, 966 F.3d at 1021.

Once again, contrary to Defendants' mischaracterization, the cases cited by Defendants actually support a finding of reliance and Article III standing. *Beyer*, cited by Defendants as "instructive in highlighting the insufficiency of Plaintiff's pleading" found reliance where the plaintiff "only allege[d] that he 'reviewed the product page' for the Second Software and does not explicitly allege that he saw the statement that the software was 'industry leading." *Beyer v. Symantec Corp.*, 333 F. Supp. 3d 966, 980 (N.D. Cal. 2018) (finding that "[n]evertheless, it is reasonable to infer for purposes of the motion to dismiss from the fact that he reviewed the product page that he saw the 'industry leading' statement on the page."). Defendants' own "instructive" authority sets a relatively low bar for pleading reliance, one which Plaintiff's allegations of reliance on express label misrepresentations certainly satisfies. The other case cited by Defendants also establishes the sufficiency of Plaintiff's pleading. In *Bronson*, the court

found that plaintiffs established reliance as to the product packaging, but not the website or print advertisements on which they did not allege they had relied. *Bronson v. Johnson & Johnson, Inc.*, No. C 12-04184 CRB, 2013 WL 1629191, at *2 (N.D. Cal. Apr. 16, 2013). The same is true here, where Plaintiff only alleges that she relied on Defendants' express label representations.

VIII. THERE IS NO FEDERAL PREEEMPTION

There are no new facts pled in Plaintiff's SAC that would change the Court's prior finding that there is no FDA primary jurisdiction or preemption. These issues were already thoroughly briefed and properly determined. *See* Original MTD Order at 12-17 ("Here, Plaintiff's claims only require the court to determine whether Defendants' product labels are false or misleading to a reasonable consumer, and those kinds of claims do not give rise to preemption."). Although Defendants' arguments only appear to reiterate its prior assertions, for the sake of completeness, Plaintiff briefly summarizes her prior briefing and the Court's analysis below.

Each of Defendants' arguments misses the central point that this is a mislabeling case focused on Defendants' false and misleading advertising statements. *See* Original MTD Order at 16 ("After all, federal law did not require Defendants to represent that their hand wipes kill 99.99 percent of germs or that they are 'hypoallergenic' and 'gentle.' Instead, these were advertising choices that Defendants made, and Plaintiff is simply challenging those choices.").

As previously determined by the Court, Section 379r does not preclude Plaintiff's claims: "Contrary to Defendants' claim, Plaintiff is not asking this Court to impose additional labeling requirements under state law that are 'different from or in addition

⁸ Once again, to the extent Defendants are permitted to "expressly adopt and incorporate[] its preemption and primary jurisdiction argument" from their original and renewed motions (MTD FAC n.10), Plaintiff likewise respectfully requests that her arguments in opposition be incorporated here. *See* Plaintiff's Opposition to Original MTD, Dkt. No. 36, at 2-13; Plaintiff's Opposition to MTD FAC, Dkt. No. 59, at 18-21.

to' the ones that the FDCA imposes. Rather, Plaintiff is merely saying that Defendants' product labeling, as it currently stands, is misleading." Original MTD Order at 15-16 (citing cases); *see also Mier*, 2021 WL 1559367, at *10 ("Plaintiff has asserted a false advertising claim by proffering evidence that shows why the Product's labelling is false or misleading . . . Plaintiff refers to scientific studies that show that hand sanitizers, including the Product, do not kill 99.99% of all germs . . . Therefore, the FDCA does not preempt Plaintiff's analogous state-law claims.").

Each of Defendants' assertions to the contrary is incorrect. Plaintiff does not seek to impose any testing or labeling requirements on Defendants. The testing cited by Plaintiff regarding the Soapopular brand hand sanitizer is simply an example illustrating the falsity of Defendants' Representations. Plaintiff takes no position in her SAC regarding how Defendants should test their Products. *See* Original MTD Order at 16 ("Rather, if proven, Plaintiff's claims would 'simply require Defendant[s] to truthfully state [their products'] efficacy or not sell its products; such relief would not impose a state requirement that is different from or in addition to, or that is otherwise not identical with that of the FDCA."") (citation omitted).

Furthermore, as previously stated, there is currently no final FDA rule that regulates the Products. *See* 21 C.F.R. § 310 at I.A. *See also* Order at 17:3-6 ("The legal status of each tentative final monograph . . . is that of a proposed rule.' Fed. Reg. 31403. Since a TFM is not law, it has no preemptive force.").

As also previously determined by this Court, there is no primary jurisdiction of the FDA. Plaintiff's state law claims "exist[] independently of [the FDCA]" and Plaintiff can bring a claim asserting that the Product labels are misleading. Original MTD Order at 15:5-13. Whether Defendants' label statements are false and misleading is a determination that is readily within the purview of this Court. *Id.* at 12-13.

IX. PLAINTIFF PROPERLY SEEKS EQUITABLE RELIEF

With complete disregard for the Court's prior finding that *Sonner* is not controlling, Defendants reiterate their incorrect argument that Plaintiff may not seek equitable relief. *See* MTD FAC Order at 23-24 ("The Court agrees with Plaintiff that *Sonner* is inapplicable because it does not apply to claims of false advertising that may result in a future harm, which Plaintiff is alleging here.").

As Plaintiff has fully briefed and the Court held, *Sonner* does not apply to claims of false advertising that may result in a future harm and does not invalidate *Davidson*, which allows a consumer to seek injunctive relief where the consumer may suffer a threat of future harm. *See id.* at 23 ("Courts applying California law continue to find that plaintiffs may seek equitable relief under California's consumer protection laws where the claims are premised on alleged future harm.") (citing cases); *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 969 (9th Cir. 2018) (a previously deceived consumer may "seek an injunction against false advertising or labeling, even though the consumer now knows or suspects that the advertising was false at the time of the original purchase, because the consumer may suffer an 'actual and imminent, not conjectural or hypothetical' threat of future harm."); *see also Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020). Plaintiff seeks relief "based on a likelihood of future harm for which there is no adequate remedy at law therefore, Plaintiff has properly sought and alleged entitlement to an equitable remedy." MTD FAC Order at 24:6-7 (citing *Davidson*). Accordingly, Plaintiff properly seeks an equitable remedy.

X. CONCLUSION

For the reasons set forth herein, Plaintiff respectfully requests that the Court deny Defendants' Motion to Dismiss in its entirety.

Case 3:20-cv-01486-TWR-BLM Document 69 Filed 05/12/22 PageID.1789 Page 30 of 31

SER-099

CERTIFICATE OF SERVICE I, Naomi B. Spector, hereby certify that I electronically filed the foregoing Opposition to Defendants' Motion to Dismiss Plaintiff's Second Amended Class Action Complaint with the Court's CM/ECF system. Notice of this filing will be served to all parties by operation of the Court's electronic filing system. Dated: May 12, 2022 /s/ Naomi B. Spector Naomi B. Spector, Esq.

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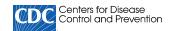
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EXHIBIT 1

Center for Disease Control and Prevention

"Hand Sanitizer Use Out and About"

https://www.cdc.gov/handwashing/hand-sanitizer-use.html



Hand Sanitizer Use Out and About

Updated November 4, 2020



During the Coronavirus Disease 19 (COVID-19) pandemic, keeping hands clean is especially important to help prevent the virus from spreading.



Germs are everywhere! They can get onto hands and items we touch during daily activities and make us sick. Cleaning hands at key times with soap and water or hand sanitizer that contains at least 60% alcohol is one of the most important steps you can take to avoid getting sick and spreading germs to those around you.

There are important differences between washing hands with soap and water and using hand sanitizer. Soap and water work to remove all types of germs from hands, while sanitizer acts by killing certain germs on the skin. Although alcoholbased hand sanitizers can quickly reduce the number of germs in many situations, they should be used in the right situations. Soap and water are more effective than hand sanitizers at removing certain kinds of germs like norovirus, *Cryptosporidium*, and *Clostridioides difficile*, as well as chemicals.

Hand sanitizers also may not remove harmful chemicals, such as pesticides and heavy metals like lead.

Handwashing reduces the amounts of all types of germs, pesticides, and metals on hands. Knowing when to clean your hands and which method to use will give you the best chance of preventing sickness.

CDC Health Advisory: Serious health problems caused by hand sanitizers containing methanol.

Learn more



Soap and Water

- · Before, during, and after preparing food
- · Before eating food
- **Before** and **after** caring for someone who is sick with vomiting or diarrhea
- . Before and after treating a cut or wound
- After using the toilet
- After changing diapers, or cleaning up a child who has used the bathroom
- After touching an animal, animal feed, or animal waste
- After handling pet food or pet treats
- After touching garbage
- If your hands are visibly dirty or greasy

Alcohol-based Hand Sanitizer

- Before and after visiting a friend or loved one in a hospital or nursing home, unless the person is sick with Clostridioides difficile (if so, use soap and water to wash hands).
- If soap and water are not readily available, use an alcohol-based hand sanitizer that contains at least 60% alcohol, and wash with soap and water as soon as you can.

DO NOT use hand sanitizer if your hands are visibly dirty or greasy—for example, after gardening, playing outdoors, fishing, or camping. If a handwashing station is available, wash your hands with soap and water instead.

After blowing your nose, coughing, or sneezing, you should clean your hands by immediately washing your hands with soap or using alcohol-based hand sanitizer to avoid spreading germs.

How should I use?

Soap and Water

- **Wet** your hands with clean running water (warm or cold), turn off the tap, and apply soap.
- Lather your hands by rubbing them together with the soap. Lather the backs of your hands, between your fingers, and under your nails.
- **Scrub** your hands for at least 20 seconds. Need a timer? Hum the "Happy Birthday" song twice.
- Rinse your hands under clean, running water.
- **Dry** your hands using a clean towel or air dry them.

Alcohol-based Hand Sanitizer

Use an alcohol-based hand sanitizer that contains at least 60% alcohol. Supervise young children when they use hand sanitizer to prevent swallowing alcohol, especially in schools and childcare facilities.

- Put enough sanitizer on your hands to cover all surfaces.
- **Rub** your hands together until they feel dry (this should take around 20 seconds).

Do NOT rinse or wipe off the hand sanitizer before it's dry; it may not work well against germs.

^{3/18/2021} Case 3:20-cv-01486-TWR-BLM Document 48-2 Filed 05/11/21 Page D. 284 Page 7 of 63

- Hand Hygiene FAQs
- Show Me the Science When & How to Use Hand Sanitizer in Community Settings
- When and How to Wash Your Hands
- Publications, Data and Statistics

Page last reviewed: November 4, 2020

EXHIBIT 2

Images of Front and Back Panels of Products



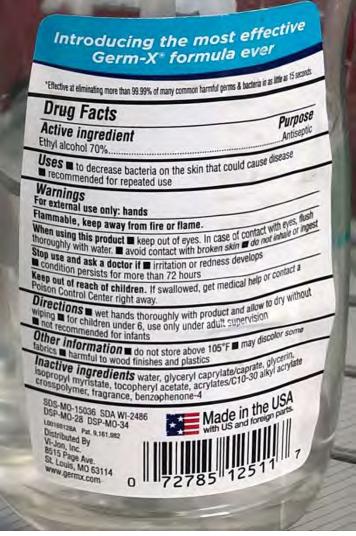


SER-109. 006











Drug Facts

Active ingredient Ethyl alcohol 62%.....Antiseptic

Purpose

Uses ■ to decrease bacteria on the skin that could cause disease recommended for repeated use

Warnings

For external use only: hands

Flammable, keep away from fire or flame.

When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin ■ do not inhale or ingest

Stop use and ask a doctor if ■ irritation and redness develop ■ condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult control without wiping ■ for children under 6, use only under adult control without wiping ■ for children under 6, use only under adult control without wiping ■ for children under 6, use only under adult control without wiping ■ for children under 6, use only under adult control without wiping ■ for children under 6, use only under adult control without wiping ■ for children under 6, use only under adult control with the children under 6 and t under adult supervision ■ not recommended for infants

Other information ■ do not store above 105°F ■ may discolor some fabrics ■ harmful to wood finishes and-

acetate, blue 1, yellow 5

Questions? 1-888-287-1915

*Effective at eliminating 99.99% of many common harmful germs and bacteria in as little and D-MO-28 DSP-MO-34 bacteria in as little as 15 seconds.

EXHIBIT 3

The New York Times

"Coronavirus Has Caused a Hand Sanitizer Shortage. What Should You Do?"

https://www.nytimes.com/2020/03/11/smarter-living/wirecutter/coronavirus-hand-sanitizer.html

The New York Times

WIRECUTTER

Coronavirus Has Caused a Hand Sanitizer Shortage. What Should You Do?

Using hand sanitizer helps prevent the spread of coronavirus. So what do you do when it's sold out?

By Ganda Suthivarakom

Ms. Suthivarakom is special projects editor for Wirecutter, a product recommendation site owned by The New York Times Company

Published March 11, 2020 Updated March 21, 2020

Alarm over coronavirus has caused a run on hand sanitizers. And now, sanitizers from Purell and other brands are exceedingly hard to come by. Where it isn't sold out, enterprising sellers are charging outrageously inflated prices simply because they can. If you don't have any hand sanitizer, you're not likely to get some while the manufacturers create enough supply to meet the frenzied demand caused by panic over coronavirus. (To be clear, we don't think anyone should panic.)

While using hand sanitizer is a smart way to slow and prevent the spread of viruses, keep in mind that washing your hands thoroughly with soap is more effective than using hand sanitizer. (Here's a fun list of choruses that work from Twitter if you don't want to sing "Happy Birthday" to reach at least 20 seconds of handwashing.) But if you're on a train and a sudden lurch forces you to grab a pole, we can understand wishing for a squirt of something purifying while you're enclosed for the rest of your trip. So what do you do if you can't get your hands on the most popular hand sanitizers? In collaboration with Wirecutter, a product review website owned by the New York Times, here's our advice:

Dos

Do wash your hands frequently and thoroughly. This is the smartest thing you can do to prevent the spread of viruses.

YOUR CORONAVIRUS TRACKER: We'll send you the latest data for	Sign Up
places you care about each day.	Sign op

Do make sure that if you are able to buy a lesser-known brand of hand sanitizer, it's made of at least 60% alcohol, as recommended by the Centers for Disease Control and Prevention. (C.D.C.) That rules out some of the so-called "botanical" options and popular kid-friendly options.

Do make sure that if you decide to try and make your own hand sanitizer, it also contains at least 60% alcohol. This recipe (two parts rubbing alcohol, one part aloe) sounds like it should achieve 60% alcohol. Keep in mind that some recipes call for using liquor (like vodka), which is usually 40% alcohol, and might not reach the threshold you need. For instance, Tito's Vodka has been urging people not to use its product in DIY sanitizer solutions.

Do dry your hands before applying any hand sanitizer. A 2019 study published in the American Society for Microbiology's publication, mSphere, found that wet mucus protected the influenza A virus, rendering hand sanitizer less effective.

Don'ts

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Don't rely on DIY recipes based solely on essential oils. They won't work.

Don't be conservative with your sanitizer, even if you're down to one small travel-size bottle. For it to work, you need to cover every surface of both hands entirely with the sanitizer and rub until dry, according to the C.D.C.

Don't use any hand sanitizer on greasy or dirty hands; it's less effective, according to the C.D.C.

Don't assume all anti-bacterial wipes will do the job. Benzalkonium chloride, the active ingredient in Wet Ones, was found to be less effective than ethanol (as in alcohol, the active ingredient in some sanitizers), hydrogen peroxide, or sodium hypochlorite on coronaviruses in an analysis of 22 studies published in February 2020.

Don't expect baby wipes to work as well as handwashing or hand sanitizer. Baby wipes don't have alcohol in them, and rubbing won't remove germs from your hands the way simple soap and clean running water can.

Sign up for the Wirecutter Weekly Newsletter and get our latest recommendations every Sunday.

A version of this article appears at Wirecutter.com.

EXHIBIT 4

Grand View Research

"Hand Sanitizer Market Size, Share & Trends Analysis Report By Product (Gel, Foam, Liquid), By Distribution Channel (Hypermarket & Supermarket, Drug Store, Specialty Store, Online), By Region, And Segment Forecasts, 2020-2027"

https://www.grandviewresearch.com/industry-analysis/hand-sanitizer-market



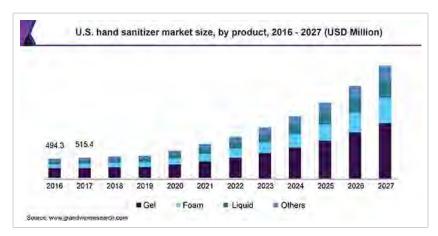
Home (/) » Beauty & Personal Care (/industry/beauty-and-personal-care) » Hand Sanitizer Market Size, Industry Report, 2020-2027



Report Overview

Search...

The global hand sanitizer market size valued at USD 2.7 billion in 2019 and is expected to grow at a compound annual growth rate (CAGR) of 22.6% from 2020 to 2027. Shifting consumer preference towards convenient hygiene products is expected to drive the market. In addition, the recent COVID-19 pandemic at the beginning of 2020 has spurred the market for hand sanitizer. The demand for hand hygiene products has been exceeding the supply in both online as well as brick and mortar sale channels worldwide owing to the global outbreak of the virus in a short time span. The outbreak has reinforced the significance of regular hand sanitizing and cleaning practices among consumers and is among the prominent factor driving the market.



To learn more about this report, request a free sample copy (/industry-analysis/hand-sanitizer-market/request/rs2)

Hand sanitizers have an advantage over conventional hand washing products as they can be applied directly without water. Also, renowned manufacturing companies such as Henkel Corporation, Unilever, and Procter and Gamble have been offering hand sanitizers in convenient packagings such as sachet and mini bottles, which can easily be carried in a bag or a pocket by the consumers. These factors have widened the scope of the market.

According to findings, there is a preference for using hand sanitizer by 77.0% of the population covered in a survey, while 23.0% claim not to use the product. The 77.0% population in the favor of using hand sanitizer is comprised of 37.5% male users and 62.5% of female users. Moreover, key manufacturers are adding to their product line in order to increase their market share with increasing awareness. For instance, as per findings, 62.0% of the population surveyed in 2017 claims to use Dettol hand sanitizer, 21.0% use Lifebuoy hand sanitizer, and 17.0% use Himalaya hand sanitizer.

Increasing awareness towards hand hygiene is gaining prominence on account of being an important measure to restrict the occurre his of the section of his prove user infections. Therefore, hand hygiene forms the most important element of personal care, thereby driving the popularity of hand san the most important element of personal care, thereby driving the popularity of hand san the section of hand care (/industry-analysis/hand-care-market) products in order to increase awareness as well as in health

issues among consumers. For instance, the WHO and FDA have taken initiatives in order to make people aware of hand hygiene and the risks associated with not maintaining the hygiene.

Moreover, the rising influence of social media and online advertisements has exposed people to the recent trends of personal care and hygiene which is also accelerating the usage of hand sanitizers among consumers. These advertisements also allow people to get exposed to information regarding cleansers and healthy lifestyles. Key companies such as Reckitt Benckiser Group plc and Hindustan Unilever are also leading among consumers with their initiatives on spreading awareness about basic hand hygiene.

Hand sanitizers come across as a beneficial product to consumers in various aspects. The extent to which it is easy to use as well as portable and convenient has made the product popular among consumers. According to studies, this product also minimizes the risk of gastrointestinal and respiratory infections among consumers. Moreover, hand sanitizers also contain ingredients that help in reducing skin dryness and irritation compared to hand washing. Furthermore, according to studies, classroom application of hand sanitizers is expected to reduce the absenteeism of students due to illness by 20%. However, the growth of the market can be hampered by the usage of chemical ingredients associated with the product causing allergies to some people. While product innovation and new product development strategies adopted by the companies to introduce organic and natural ingredients in the manufacturing of hand sanitizers, which will gain the trust of consumers.

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Product Insights

The gel based hand sanitizer segment dominated with a share of more than 49.0% of the global market in 2019. Gel sanitizers are usually thin and watery in formulation and therefore provide the convenience of getting spread easily and penetrate into the skin to kill most of the bacteria. Easy product availability and wider access to this type of hand sanitizer are driving the growth of the segment in the market in the last few years. The product results in decreased microbial populations in different ways. Moreover, the inclusion of different flavors affecting the fragrance is driving segment growth in the hand sanitizer market. For instance, in 2017, Himalaya Wellness has launched new sanitizers which are available in fruit flavors including strawberry, green apple, litchi, and orange.

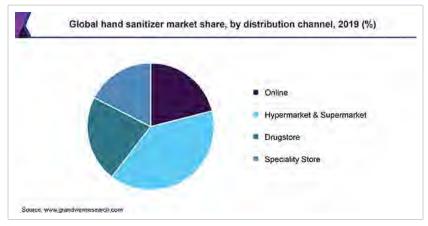
The foam based hand sanitizer segment is expected to dominate the market with a revenue based CAGR of 23.1% from 2020 to 2027. The product is gaining prominence in the market owing to its ability to penetrate the skin and stay there for a longer period of time. Foam based sanitizers provide easy application on hands as it does not needs to get rubbed off and thus provides the convenience of saving time. This product is expected to witness a surge in demand owing to its greater convenience of handling. For instance, in April 2018, Arrow Solutions launched KR10 Hand Sanitizer Foam, which is an alcohol free foam sanitizer designed for frequent use.

Distribution Channel Insights

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Hypermarket and supermarket channels accounted for the largest share of more than 39.3% of the market in 2019. An increasing pumber of hypermarkets and supermarkets across various regions have experienced a surge in the distribution of hand sanitizers in the market. However, this channel also supplies quick some supplies of scanning the product before buying which helps them choose the right product. Moreover, this channel also supplies quick

access to the product compared to online channels where consumers are made to wait for the delivery of the product.



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Online distribution channel is projected to witness a CAGR of 23.2% from 2020 to 2027 owing to the increasing influence of digital media and marketing. Increasing internet penetration in various countries such as India, China, Mexico, and Brazil has developed the market for online sales channels from the last three to four years. Moreover, online retailers including Amazon, Walmart, Alibaba and other such service providers are focusing on the continuous availability of personal care products across the globe. Online retail channels are widely used in developed countries such as U.S., Germany, and U.K., for purchasing consumer goods and unique personal care products. It is poised to emerge as a steady revenue generating source for these product categories over the forecast period. Promising growth exhibited by e-commerce platforms in emerging countries, including India and China, is compelling manufacturers to reorient their retail strategies for these countries.

Regional Insights

North America dominated the market and accounted for a revenue share of 32.2% in 2019. Growing concern for health and hygiene maintenance by the majority of the population in the region is expected to drive the market. Wider product availability with increased penetration of online as well as offline channels is driving the growth of the market in the region. This region with a greater number of market players' witnesses' highest penetration of different forms of hand sanitizers such as gel based, foam based, spray, and wipes. Moreover, U.S. dominates the market with more willingness of consumers to spend on personal care and hygiene products.

Asia Pacific is expected to witness the fastest CAGR of 23.5% from 2020 to 2027. The growth is attributed to the growing awareness about hygiene among consumers. Therefore, innovative and different types of personal care and hygiene products are available in the market stressing on convenience factors for consumers. The increasing dominance of online shopping has reshaped the growth of the market in the region and is expected to fuel the demand for hand sanitizers in the future years. For instance, online websites such as Amazon, Flipkart, Grofers, and other such online delivery service firms are offering different types of hand hygiene products.

Key Companies & Market Share Insights

The market is highly competitive in nature. Companies are focusing on expanding their production capacity and are adopting innovative technologies to meet consumer demand for hand sanitizers. Some of the prominent players in the hand sanitizer market include:

- · Reckitt Benckiser Group plc
- · Procter and Gamble
- · The Himalaya Drug Company
- · GOJO Industries, Inc.
- · Henkel AG and Company
- Unilever
- Vi-Jon
- · Chattem, Inc.
- · Best Sanitizers, Inc.
- Kutol

Hand Sanitizer Market Report Scope

	Report Attribute	Details	This site uses cookies to improve user
	Market size value in 2020	USD 3.3 billion	experience. More Info (/info/privacy-policy)
	Revenue forecast in 2027	USD 13.7 billion	(X)
r	randviewresearch.com/industry-analysis/hand-sanitizer-market		SER-119.016 3

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Growth Rate	CAGR of 22.6% from 2020 to 2027
Base year for estimation	2019
Historical data	2016 - 2018
Forecast period	2020 - 2027
Quantitative units	Revenue in USD million and CAGR from 2020 to 2027
Report coverage	Revenue forecast, company ranking, competitive landscape, growth factors, and trends
Segments covered	Product, distribution channel, region
Regional scope	North America; Europe; Asia Pacific; Central & South America; Middle East & Africa
Country scope	U.S.; Germany; U.K.; China; India; Brazil
Key companies profiled	Reckitt Benckiser Group plc; Procter and Gamble; The Himalaya Drug Company; GOJO Industries, Inc.; Henkel AG and Company; Unilever; Vi-Jon; Chattem, Inc.; Best Sanitizers, Inc.; Kutol
Customization scope	Free report customization (equivalent up to 8 analysts working days) with purchase. Addition or alteration to country, regional & segment scope.
Pricing and purchase options	Avail customized purchase options to meet your exact research needs. Explore purchase options (/checkout/select-license/hand-sanitizer-market)

Segments Covered in the Report

This report forecasts revenue growth at global, regional, and country levels and provides an analysis of the latest industry trends in each of the subsegments from 2016 to 2027. For the purpose of this study, Grand View Research has segmented the global hand sanitizer market report on the basis of product, distribution channel, and region:

- Product Outlook (Revenue, USD Million, 2016 2027)
 - Gel
 - Foam
 - Liquid
 - · Others
- · Distribution Channel Outlook (Revenue, USD Million, 2016 2027)
 - Hypermarket & Supermarket
 - · Specialty Store
 - Drugs Store
 - Online
- Regional Outlook (Revenue, USD Million, 2016 2027)
 - North America
 - 。U.S.
 - Europe
 - Germany
 - U.K
 - · Asia Pacific
 - China
 - India
 - · Central & South America
 - Brazil
 - Middle East & Africa

Frequently Asked Questions About This Report

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How big is the hand sanitizer market?	•
What is the hand sanitizer market growth?	•
Which segment accounted for the largest hand sanitizer market share?	•
Who are the key players in hand sanitizer market?	•
What are the factors driving the hand sanitizer market?	•

The report addresses: The report addresses: Expected marker growth until 2027 To repeat on now marker divers, restrains, and future opportunities will anect the marker nyman or Singmants and regions that will drive or load marker growth and why: Comprehensive mapping of the compositive lanceases Indeet more? Need more? Get more details about what's inside (ally to us about quatemizing the report)

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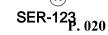


EXHIBIT 5

Declaration of Anthony Moreno In Support of Second Amended Complaint and Regarding Venue

3:20-CV-01446-

DECLARATION OF PLAINTIFF ANTHONY MORENO

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- 1. I am a named-plaintiff and a prospective class member in the above-entitled action.
- 2. I am an adult, over 18 years old. I have personal knowledge of the facts stated herein and could competently testify thereto if called upon to do so.
- 3. I am currently a resident of San Diego County, California. The Complaint filed in this matter contains causes of action for violations of: (1) Unfair and Unlawful Business Acts and Practices, Cal. Business & Professions Code §§ 17200 *et seq.* (the "UCL"); (2) Deceptive Advertising Practices, Cal. Business & Professions Code §§ 17500 *et seq.* (the "FAL"); (3) California's Consumer Legal Remedies Act, Cal. Civil Code §§ 1750 *et seq.* (the "CLRA"); (4) Breach of Express Warranty; and (5) Quasi Contract. These causes of action arise out of Defendant Vi-Jon, Inc.'s deceptive, unfair, and false merchandising practices with respect to its alcohol-based hand
- sanitizers, including sanitizers sold under the following brands: (i) CVS health and/or CVS pharmacy ("CVS"), (ii) equate, (iii) germ-X, and (iv) Walgreen Co. (collectively the "Products").
 - 4. California Civil Code § 1780(d) provides that a plaintiff seeking to bring a claim under Section 1780(a) of the California Consumer Legal Remedies Act may commence that action "in the county in which the person against whom it is brought resides, has his or her principal place of business, or is doing business, or in the county where the transaction or any substantial portion thereof occurred."
 - 5. I purchased the Products at issue in San Diego, California.
 - 6. Accordingly, the Complaint filed in the above-entitled action is filed in the proper venue pursuant to Civil Code § 1780(d).
 - 7. I purchased the Products in late 2019 and/or early 2020. To the best of my recollection, I purchased the Products during the time period between November 2019 through February 2020.
 - 8. I purchased the CVS product at a CVS store located in San Diego, California.

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- The CVS Product states on the front panel "Kills 99.99% of germs." I purchased the CVS product in an 8 fluid ounce bottle. To the best of my knowledge, the purchase price of the product was approximately \$3.99.
- 9. I purchased the equate product at a Walmart store located in San Diego, California. I purchased the equate product in a 34 fluid ounce bottle. The equate product states on the front panel "KILLS 99.99% OF GERMS." To the best of my knowledge, the purchase price of the product was approximately \$3.97.
- 10. I purchased the germ-X product at a Walmart store located in San Diego, California. I purchased the germ-X product in a 12 fluid ounce bottle. The germ-x product states on the front panel that it is a "MORE EFFECTIVE FORMULA" and that it "Kills more than 99.99% of germs." To the best of my knowledge, the purchase price of the product was approximately \$2.66.
 - 11. Images of the purchased equate and germ-X products are attached hereto.
- 12. I purchased the Walgreens product at a Walgreens store located in San Diego, California. I purchased the Walgreens product in an 8 fluid ounce bottle. The front panel of the Walgreen product states that it "Kills more than 99.99% of germs." To the best of my knowledge, the purchase price of the product was approximately \$2.99.
 - 13. An image of the Walgreens product is attached hereto.
- 14. At the time of purchase, I viewed the label representations, including the statements on the front panels that the Product(s) "Kills 99.99% of germs" and "Kills more than 99.99% of germs" (the "Representations"). I relied on these Representations in purchasing the Products.
- 15. At the time I purchased the Products I did not know that the Representations were false and misleading.
- 16. If I had known that the Representations were false and misleading, I would not have purchased the Products or would have purchased them on different terms.
 - 17. I purchased hand sanitizers prior to purchasing the specific Products described

above.

- 18. During one or more hand sanitizer purchases, I viewed the following statement on the back panel: "Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds" (the "Back Panel Statement").
- 19. I do not specifically recall whether I viewed the Back Panel Statement at the time I purchased the Products at issue, but I had viewed the Statement prior to the purchase of the Products.
- 20. At the time I viewed the Back Panel Statement and at the time of purchase of the Products, the Statement did not make me aware that the Representations on the front panel were false and misleading.
- 21. At the time of purchase of the Products, I did not know that the Back Panel Statement was also false and misleading.
- 22. If I had known that the Back Panel Statement was false and misleading, I would not have purchased the Products or would have purchased them on different terms.
- 23. In addition, at the time I purchased the Products, I did not know that the Products were misbranded under the law and therefore not capable of being legally sold, delivered, held or received in commerce.
- 24. If I had known that the Products were misbranded under the law and therefore not capable of being legally sold, delivered, held or received in commerce I would not have purchased the Products.

I declare under the penalty of perjury under laws of the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on March 23, 2021, in San Diego, California.







EXHIBIT 6

BestLife

"12 Surprising Germs Hand Sanitizer Won't Kill"

https://bestlifeonline.com/hand-sanitizer-germs/



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12 Surprising Germs Hand Sanitizer Won't Kill

YOUR FRESHLY SANITIZED HANDS AREN'T AS CLEAN AS YOU THINK.

By MORGAN GREENWALD MAY 8, 2019



Hand sanitizer (https://bestlifeonline.com/downsides-of-hand-sanitizer/) is a daily staple for parents on diaper duty, commuters (https://bestlifeonline.com/traffic-commute-times/) who hold those rarely-cleaned handle bars on buses and subways, and many other people in between. In fact, according to global information company NPD Group (https://www.npd.com/wps/portal/npd/us/news/press-releases/2018/hand-cleaner-sales-rise-in-the-us-during-fluseason-reports-npd-group/), hand sanitizer sales in the United States shot up 37 percent from 2017 to 2018 alone. And while it's perfectly fine to turn to this bottled product as a last resort, you shouldn't opt for hand sanitizer over washing your hands (https://bestlifeonline.com/heres-how-youre-washing-your-hands-all-wrong/) in the sink if there's clean water and soap available to you.

As it turns out, there's a reason why most hand sanitizer companies don't claim to kill 100 percent of germs and bacteria: Because they don't. Keep reading to discover some of the state of the for hand sanitizer instead of soap and water.

1 | Norovirus



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According to the Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/norovirus/index.html), norovirus is a "very contagious virus" that can be spread via direct contact, contaminated food or drinks, and contaminated surfaces. And while thoroughly washing your hands (and your produce) is a good way to ensure your safety, using alcohol-based hand sanitizer isn't quite as effective.

In one 2011 study published in the American Journal of Infection Control (https://www.ncbi.nlm.nih.gov/pubmed/21411187), researchers analyzed data from health departments in three states and found that the facilities that relied on hand sanitizer were more likely to experience a norovirus outbreak than those that favored hand-washing.

2 | HPV



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While HPV is primarily considered a sexually transmitted infection, individuals can still contract the disease non-sexually, including through childbirth, kissing, diaper changes, and other forms of close contact, according to a 2017 study published in The Journal of Obstetrics and Gynaecology Research

(https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/jog.13248). And unfortunately, this is one virus hand sanitizer simply can't touch.

In fact, according to one 2014 study published in the Journal of Antimicrobial Chemotherapy (https://academic.oup.com/jac/article/69/6/1546/831861), the disinfectants used in hand sanitizer "do nothing for preventing the spread of human papillomavirus," as study author Craig Meyers noted in a press release (https://news.psu.edu/story/303743/2014/02/12/research/popular-disinfectants-do-not-kill-hpv).

3 | Giardia



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Giardia is a microscopic parasite that causes a nasty diarrheal illness known as giardiasis. Though people most commonly get giardiasis from a contaminated water supply or food source, it is just as possible to contract the illness from person-toperson contact should someone have microscopic amounts of fecal matter on their hands. And don't think that using hand sanitizer will clear your hands of this parasite; according to the Mayo Clinic (https://www.mayoclinic.org/diseasesconditions/giardia-infection/symptoms-causes/syc-20372786), alcohol-based sanitizers are an ineffective preventative measure (https://bestlifeonline.com/lower-heart-attack-risk/) against the cysts responsible for giardia's transmission.

4 | Clostridium Difficile



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If you want to avoid dealing with the painful symptoms (https://bestlifeonline.com/subtle-cancer-symptoms/) and illnesses associated with Clostridium difficile (C. difficile)—a type of bacterium that can cause everything from diarrhea to colitis then you'll want to wash your hands rather than relying on sanitizer. One 2009 study published in the journal *Infection* Control & Hospital Epidemiology (https://www.ncbi.nlm.nih.gov/pubmed/19715426) tested the efficacy of several different hand-washing methods to eliminate C. difficile particles. The researchers found that using an alcohol-based hand rub was as ineffective as doing nothing at all. Conversely, warm water with plain soap proved to be the most effective method for removing the bacteria.

5 | Ara h1



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Ara h1 is one of the most common allergens found in peanuts, meaning people with a peanut allergy (https://bestlifeonline.com/foods-get-rid-allergies/) need to avoid it at all costs. Unfortunately, when people use hand sanitizer instead of soap to wash up after touching peanut products, Ara h1 frequently stays on their skin. That's according to a 2004 study published in the *Journal of Allergy and Clinical Immunology* (https://www.ncbi.nlm.nih.gov/pubmed/15131582), which found that approximately 50 percent of subjects who used hand

(https://www.ncbi.nlm.nih.gov/pubmed/15131582), which found that approximately 50 percent of subjects who used hand sanitizer after touching peanut butter still had traces of Ara h1 on their palms.

As study author **Robert A. Wood**, M.D., explained in a press release (https://www.hopkinsmedicine.org/Press_releases/2004/05_08b_04.html), these sanitizers don't eliminate the allergen, but "spread it around" instead.

6 | Cryptosporidum Parvum



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Cryptosporidium parvum (C. parvum) is a type of parasite that causes cryptosporidiosis, a diarrhea-inducing disease, in the intestinal tract. And using hand sanitizer won't rid your dirty palms of this infectious agent, either.

In a landmark 1999 study published in the journal Gastrointestinal Endoscopy (https://www.ncbi.nlm.nih.gov/pubmed/10228259), only two of the more than nine disinfectants tested were able to inactivate the parasite. "Most high-level disinfectants... have limited efficacy against C. parvum," the study authors concluded.

7 | Enterococcus Faecium



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Even if your doctor (https://bestlifeonline.com/stop-lying-to-your-doctor/) uses all the hand sanitizer in the world, they might still be carrying around bacteria like Enterococcus faecium (E. faecium), which can affect the health of everything from your bladder to your heart (https://bestlifeonline.com/tag/heart-health/). Though alcohol-based hand sanitizers were previously believed to safeguard against many germs, it turns out, they're no match for Enterococcus faecium.

One 2018 study published in the journal $Science\ Translational\ Medicine$

(https://stm.sciencemag.org/content/10/452/eaar6115) tested the tolerance of several E. faecium strains against sanitizer and found that samples collected between 2010 and 2015 were 10 times more resistant to the product's supposedly-sanitizing effects than those collected between 1997 and 2010.

8 | Poliovirus



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As recently as the early 1950s, prior to the widespread availability of the vaccine, poliovirus was responsible for the paralyzation of more than 15,000 people each year in the United States, according to the CDC (https://www.cdc.gov/polio/us/index.html). And with polio returning to countries where it had previously been eradicated (including a World Health Organization (https://www.who.int/csr/don/20-February-2019-polio-png/en/)-reported outbreak in Papua New Guinea in 2018), people are desperate for ways to reduce the virus' spread. Sadly, this is one illness that alcohol-based hand sanitizers don't protect against. Since poliovirus is a type of non-enveloped virus that can last longer in the environment, it's therefore highly contagious.

So how do we know that typical hand sanitizers don't work against poliovirus? Well, when researchers from The Dental College of Georgia (http://www.heraldopenaccess.us/fulltext/Antivirals-Antiretrovirals-Research-&-Therapy/Virucidal-Capacity-of-Novel-ProtecTeaV-Sanitizer-Formulations-Containing-Lipophilic-Epigallocatechin-3-Gallate-%28EGCG%29.php) compared the efficacy of their green tea hand sanitizer against that of alcohol-based hand sanitizers in 2016, they found that their green tea product (https://fave.co/2YgT983) was 100 times more effective in immobilizing poliovirus-1 than what is currently mandated. On top of that, two commonly-used hand sanitizers tested were less effective at reducing the virus's potential to infect others.

9 | MRSA



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MRSA, or methicillin-resistant Staphylococcus aureus, is a type of bacteria that can cause potentially fatal infections. And, as its name suggests, these infections do not respond to the antibiotic methicillin. However, that's not the only reason you should fear MRSA. Though some hand sanitizers claim to protect against the bacterium, the U.S. Food and Drug Administration (FDA) (https://www.fda.gov/consumers/consumer-updates/hand-sanitizers-carry-unproven-claims-prevent-mrsa-infections) warned back in 2011 that "these statements are unproven."

"Consumers are being misled if they think these products you can buy in a drug store or from other places will protect them from a potentially deadly infection," noted **Deborah Autor**, compliance director at the FDA's Center for Drug Evaluation and Research.

10 | Pseudomonas Aeruginosa



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Pseudomonas aeruginosa (P. aeruginosa) is a rod-shaped bacterium that can cause everything from ear infections to pneumonia. Though some hand sanitizer brands have proven effective against it, others are considerably less potent. In one 2018 study published in the *Journal of Clinical Case Reports* (https://www.omicsonline.org/open-access/comparative-studies-on-the-antibacterial-activity-of-alcoholbased-hand-sanitizers-against-bacteria-isolates-from-the-hands-of-unde-2165-7920-10001143-103098.html#27), for instance, Dettol sanitizer—a hand sanitizer that claims to kill 99.9 percent of germs—was found to be an inadequate line of defense against P. aeruginosa. When it comes to this type of bacteria, hand sanitizer is a total toss-up, so it's better just to wash your hands if and when you come in contact with it.

11 | Staphylococcus epidermidis



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Don't rely on hand sanitizer to protect you from Staphylococcus (S. epidermidis). In the same 2018 study from the Journal of Clinical Case Reports, researchers found that, out of the five alcohol-based sanitizers they tested, only three were able to inhibit the growth of S. epidermidis. In other words, if you were to go to the store right now and buy a random bottle of hand sanitizer without looking at the brand name, you'd have a 40 percent chance of buying one that doesn't protect against this bacterium.

12 | Escherichia Coli



Shutterstock

If you're at all familiar with the bacterium E. coli, which the CDC (https://www.cdc.gov/ecoli/2018/0157h7-04-18/index.html) linked to five deaths in the United States during a 2018 outbreak, then you already know that you want to avoid it at all costs. However, using hand sanitizer isn't enough to rid your hands of this germ, especially if you work in an environment where you're in regular contact with raw food.

Per one 2016 meta-analysis published in the Journal of Food Protection

(https://jfoodprotection.org/doi/full/10.4315/0362-028X.JFP-15-492), the E. coli reduction achieved by hand sanitizer is "consistently lower than that obtained with water and soap." What's more, when researchers from Procter & Gamble (https://jfoodprotection.org/doi/pdfplus/10.4315/0362-028X-63.4.495) tested plain soap, hand sanitizer, and a combination of the two on people who had just handled raw chicken and beef, they found that plain soap was most effective at eliminating the E. coli threat. And for more helpful health tips, check out Exactly How Far You Need to Stand from Someone Sick to Avoid Getting the Flu (https://bestlifeonline.com/how-far-can-flu-germs-spread/).

To discover more amazing secrets about living your best life, click here (https://www.instagram.com/bestlifeonline/) to follow us on Instagram!

FILED UNDER CLEANING • HEALTH ADVICE

Bode Science Center

"Nonenveloped viruses"

https://www.bode-science-center.com/center/glossary/nonenveloped-viruses.html

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BODE SCIENCE CENTER. Research for infection protection.

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Relevant pathogens from A-Z

E-Learning

Hygiene Measures

Hand Hygiene

Surface Hygiene

Skin Antisepsis

Reprocessing of Medical Devices

Expert Knowledge

Norms & Listings

Glossary

Nonenveloped viruses

Cell parasites that do not have viral envelopes covering their central Capsid. Noroviruses but also rota- and adenoviruses are typical representatives. In contrast to Enveloped viruses, nonenveloped viruses are characterised by a higher resistance to chemical, physical procedures and other environmental influences and, if applicable, require the use of particularly powerful disinfectants that possess virucidal activity.



Capsid of a nonenveloped virus

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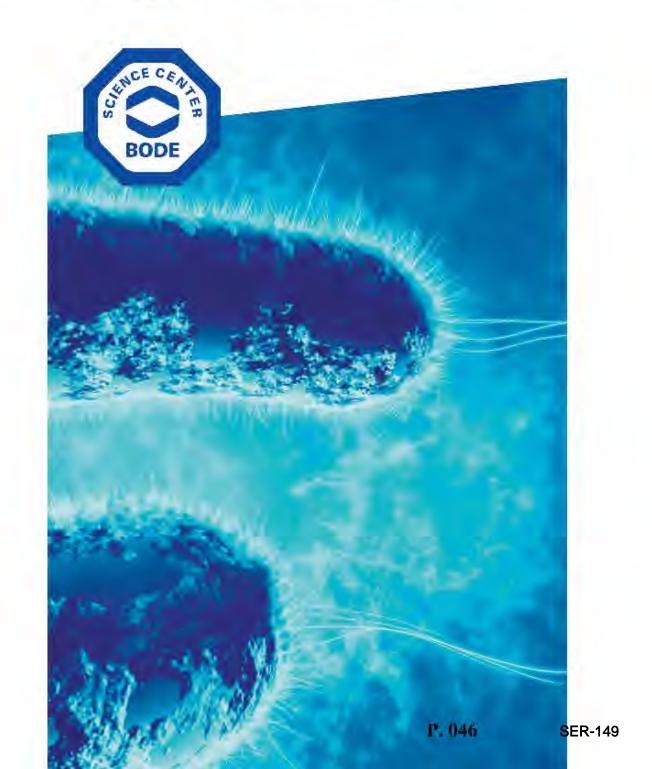
Excellence for Hygiene and Infection Control

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BODE SCIENCE CENTER

Your centre of excellence for hygiene and infection control



BODE SCIENCE CENTER

Scientific expertise – safe applications

Since 2011, BODE SCIENCE CENTER – the scientific centre of excellence of PAUL HARTMANN AG – has dealt with current issues related to hygiene and infection prevention, mainly focussing on evidence-based solutions to provide better protection for patients, healthcare workers and consumers.



Well-founded know-how and professional solutions

To improve patient protection, BODE SCIENCE CENTER systematically puts emphasis on making infection control knowledge and measures available and improve them in daily routine. Hand hygiene is not only the most effective measure to prevent nosocomial infections, but can also be implemented immediately. One important aspect: recognise and eliminate compliance barriers.



Research projects and co-operations

Practical solutions are the focus of BODE SCIENCE CENTER. Hence, the scientific centre of excellence conducts own research projects, on improving compliance, multidrug-resistant pathogens, optimised working processes and much more. For this, BODE SCIENCE CENTER closely co-operates with partners from clinical practice, for example with the University Medical Center Hamburg-Eppendorf, Germany.

Pioneer in hand hygiene

With its work BODE SCIENCE CENTER has paved the way in the field of hand hygiene and has achieved key successes — for example with the responsible rub-in method for hygienic hand disinfection, which is also recommended by the German "AKTION Saubere Hände" (Clean Hands Campaign). Additionally, the projects are about new standards such as the integration of hygienic measures into standard operating procedures (SOPs) for routine nursing and medical activities as well as psychological insights into compliance.





Events with leading experts

Together with renowned representatives from research and practice BODE SCIENCE CENTER regularly holds expert symposiums to address current topics. From special hygiene strategies to contain antibiotic-resistant pathogens to the role of skin health in infection protection and optimised hygiene thanks to improved processes: the symposia deal with and answer questions that health care, patients and consumers are concerned with.

These include:

- hygiene strategies along the patient journey
- skin health for enhanced infection protection
- patient protection through improved processes
- hospital-acquired infection and hand hygiene



Extensive online knowledge pool

BODE SCIENCE CENTER offers a comprehensive web portal, providing well-founded information on infection protection. Discover the varied range of contents and offerings:

- certified e-learning
- hygiene management for differing infectious diseases
- section with frequently asked questions (FAQs)
- pathogen search from Acinetobacter to Zika virus
- brief summaries of recent studies
- Informative articles on hand hygiene, surface hygiene, skin antisepsis and the reprocessing of medical devices
- concentrate calculator for the preparation of working solutions
- and much more.

We are at your service:

Our experts answer your questions – on the phone or via e-mail: +49 (0)40 54006-111 contact@bode-science-center.de

Mon-Thurs: 8:00 to 16:30 Fri: 8:00 to 15:00



Scientific expertise – safe applications

Explore the extensive range of information and suggestions at www.bode-science-center.com

Up-to-date information, study abstracts, e-learning tool, hygiene measures, extensive pathogen search - just a click away.



Bode Science Center

Database of Relevant Pathogens

https://www.bode-science-center.com/center/relevant-pathogens-from-a-z.html

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Relevant pathogens from A-Z

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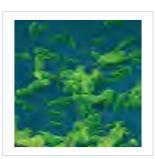
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Parasites

Due to their clinical relevance selected parasites have been added to the pathogen search. However, they cannot be inactivated by chemical disinfectants typically used in hospitals.





Pathogen search

The A-to-Z database includes compact background information on each pathogen: its family, its prevalence, most common infections that it triggers, its main transmission paths, recommendations on disinfection, and, where appropriate, the pathogen's resistance pattern.

A disinfection procedure's necessary spectrum of effect is normally determined by the pathogen (e.g. Coxsackievirus). In case you have no data available on the pathogen concerned, this page will serve as guide: for your convenience, the overview also includes the disinfectants' spectrum of activity necessary to kill the respective microorganism (e.g. virucidal for Coxsackivirus).

Always up to date:

The A-to-Z database is constantly being updated with relevant pathogens and aligned with information by the German Robert Koch-Institute (RKI) and the World Health Organization (WHO).

Thus, it contains all pathogens prioritised by RKI and the most relevant antibioticresistant bacteria listed by WHO.

Search

Clinically relevant pathogens in alphabetical order

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Α

Acinetobacter baumannii Bactericidal Acinetobacter Iwoffii Bactericidal

Acinetobacter spp. (incl. MDR) Bactericidal

Actinomycetes Bactericidal

Adenovirus Virucidal

Aeromonas spp. Bactericidal

African Swine Fever-Vius Virucidal against enveloped viruses

Alcaligenes faecalis Bactericidal

Alcaligenes spp./Achromobacter spp. Bactericidal

Alcaligenes xylosoxidans (incl. ESBL/MRGN) Bactericidal

Arbovirus Virucidal against enveloped viruses

Ascaris lumbricoides Specific disinfectants effective against parasites are required

Aspergillus spp. Fungicidal

Astrovirus Virucidal

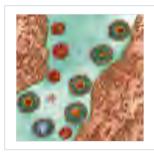
В

Bacillus anthracis Sporicidal
Bacillus cereus Sporicidal
Bacillus subtilis Sporicidal
Bacteriodes fragilis Bactericidal
Bartonella quintana Bactericidal

Blastocystis hominis Specific disinfectants effective against parasites are required

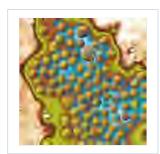
Bordetella pertussis Bactericidal
Borrelia burgdorferi Bactericidal
Borrelia duttoni Bactericidal

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Borrelia recurrentis Bactericidal
Brevundimonas diminuta Bactericidal
Brevundimonas vesicularis Bactericidal
Brucella spp. Bactericidal
Burkholderia cepacia (incl. MDR) Bactericidal
Burkholderia mallei Bactericidal

С

Campylobacter jejuni / coli Bactericidal
Candida albicans Yeasticidal
Candida auris Yeasticidal
Candida krusei Yeasticidal

Burkholderia pseudomallei Bactericidal

Chikungunya virus (CHIKV) Virucidal against enveloped viruses

Chlamydia pneumoniae Bactericidal
Chlamydia psittaci Bactericidal
Chlamydia trachomatis Bactericidal
Citrobacter spp. Bactericidal

Candida parapsilosis Yeasticidal

Clostridium botulinum Sporicidal
Clostridium difficile Sporicidal
Clostridium perfringens Sporicidal
Clostridium tetani Sporicidal

Coronavirus (incl. 2019-nCoV, SARS- und MERS-CoV) Virucidal against enveloped viruses

Corynebacterium diphtheriae Bactericidal

Corynebacterium pseudotuberculosis Bactericidal

Corynebacterium spp. Bactericidal Corynebacterium ulcerans Bactericidal Coxiella burnetii Bactericidal

Coxiella burnetii Bactericidal
Coxsackievirus Virucidal

Crimean-Congo haemorrhagic fever virus Virucidal against enveloped viruses

Cryptococcus neoformans Yeasticidal

Cryptosporidium hominisSpecific disinfectants effective against parasites are requiredCryptosporidium parvumSpecific disinfectants effective against parasites are requiredCyclospora cayetanensisSpecific disinfectants effective against parasites are requiredCytomegalovirusCMVVirucidal against enveloped viruses

D

Dengue virus Virucidal against enveloped viruses

Dientamoeba fragilis Specific disinfectants effective against parasites are required

Ε

Ebola virus Virucidal against enveloped viruses

Echinococcus spp. Specific disinfectants effective against parasites are required

Echovirus Virucidal

Entamoeba dispar Specific disinfectants effective against parasites are required

Entamoeba histolytica Specific disinfectants effective against parasites are required

Enterobacter aerogenes Bactericidal

Enterobacter cloacae (incl. ESBL/MRGN) Bactericidal

Enterobius vermicularis Specific disinfectants effective against parasites are required

Enterococcus faecalis (incl. VRE) Bactericidal Enterococcus faecium (incl. VRE) Bactericidal

Enterococcus hirae Bactericidal
Epidermophyton spp. Fungicidal

Epstein-Barr virus EBV Virucidal against enveloped viruses

Escherichia coli

(incl. EHEC, EPEC, ETEC, EIEC, EAEC, ESBL/MRGN, DAEC) Bactericidal

F

Filarial worms Specific disinfectants effective against parasites are required

Foot-and-mouth disease virus (FMDV) Virucidal

Francisella tularensis Bactericidal

Giardia lamblia Specific disinfectants effective against parasites are required

```
н
Haemophilus influenzae Bactericidal
Hantavirus Virucidal against enveloped viruses
Helicobacter pylori Bactericidal
Helminths (Worms) Specific disinfectants effective against parasites are required
Hepatitis A virus HAV Virucidal
Hepatitis B virus HBV Virucidal against enveloped viruses
Hepatitis C virus HCV Virucidal against enveloped viruses
Hepatitis D virus Virucidal against enveloped viruses
Hepatitis E virus Virucidal
Herpes simplex virus HSV Virucidal against enveloped viruses
Histoplasma capsulatum Fungicidal
HTLV-1 Virucidal against enveloped viruses
Human enterovirus 71 Virucidal
Human herpesvirus 6 (HHV-6) Virucidal against enveloped viruses
Human herpesvirus 7 (HHV-7) Virucidal against enveloped viruses
Human herpesvirus 8 (HHV-8) Virucidal against enveloped viruses
Human immunodeficiency virus HIV Virucidal against enveloped viruses
Human metapneumovirus Virucidal against enveloped viruses
Human papillomavirus Virucidal
Hymenolepsis nana Specific disinfectants effective against parasites are required
Influenza virus (incl. A(H1N1), A(H1N1)pdm09, A(H3N2), A(H5N1), A(H5N5), A(H5N6),
A(H5N8), A(H7N9), A(H10N8)) Virucidal against enveloped viruses
J
Klebsiella granulomatis Bactericidal
Klebsiella oxytoca (incl. ESBL/MRGN) Bactericidal
Klebsiella pneumoniae MDR (incl. ESBL/MRGN) Bactericidal
1
Lassa virus Virucidal against enveloped viruses
Leclercia adecarboxylata Bactericidal
Legionella pneumophila Bactericidal
Leishmania spp. Specific disinfectants effective against parasites are required
Leptospira interrogans Bactericidal
Leuconostoc pseudomesenteroides Bactericidal
Listeria monocytogenes Bactericidal
М
Marburg virus Virucidal against enveloped viruses
Measles virus Virucidal against enveloped viruses
Mengla virus Virucidal against enveloped viruses
Micrococcus luteus Bactericidal
Microsporum spp. Fungicidal
Molluscipoxvirus Virucidal against enveloped viruses
```

Moraxella catarrhalis Bactericidal Morganella spp. Bactericidal Mumps virus Virucidal against enveloped viruses Mycobacterium basiliense sp. nov. Mycobactericidal Mycobacterium chimaera Mycobactericidal Mycobacterium leprae Mycobactericidal Mycobacterium tuberculosis (incl. MDR, XDR, XXDR and TDR) Tuberculocidal Mycoplasma genitalium Bactericidal Mycoplasma pneumoniae Bactericidal

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Naegleria fowleri Specific disinfectants effective against parasites are required

Neisseria meningitidis Bactericidal Neisseria gonorrhoeae Bactericidal

Nipah virus Virucidal against enveloped viruses

Norovirus Virucidal

O

Opisthorchis viverrini Specific disinfectants effective against parasites are required Orientia tsutsugamushi Bactericidal

Р

Pantoea agglomerans Bactericidal

Paracoccus yeei Bactericidal

Parainfluenza virus Virucidal against enveloped viruses

Parvovirus Virucidal

Pediculus humanus capitis Specific disinfectants effective against parasites are required Pediculus humanus corporis Specific disinfectants effective against parasites are required

Plasmodium spp. Specific disinfectants effective against parasites are required

Pneumocystis jiroveci Fungicidal

Poliovirus Virucidal
Polyomavirus Virucidal
Prevotella spp. Bactericidal

Prions

Propionibacterium species Bactericidal

Proteus mirabilis (incl. ESBL/MRGN) Bactericidal

Proteus vulgaris Bactericidal
Providencia rettgeri Bactericidal
Providencia stuartii Bactericidal
Pseudomonas aeruginosa Bactericidal
Pseudomonas spp. Bactericidal

Q

R

Rabies virus Virucidal against enveloped viruses

Ralstonia spp. Bactericidal

Respiratory syncytial virus RSV Virucidal against enveloped viruses

Rhinovirus Virucidal

Rickettsia prowazekii Bactericidal Rickettsia typhi Bactericidal Roseomonas gilardii Bactericidal

Rotavirus Virucidal

Rubella virus Virucidal against enveloped viruses

S

Schistosoma mansoni Specific disinfectants effective against parasites are required

Salmonella enteritidis Bactericidal
Salmonella paratyphi Bactericidal
Salmonella spp. Bactericidal
Salmonella typhi Bactericidal
Salmonella typhimurium Bactericidal

Sarcoptes scabiei (Itch mite) Specific disinfectants effective against parasites are required

Sapovirus Virucidal

Serratia marcescens (incl. ESBL/MRGN) Bactericidal

Shigella sonnei Bactericidal

Sphingomonas species Bactericidal

Staphylococcus aureus (incl. MRSA, VRSA) Bactericidal

Staphylococcus capitis Bactericidal

Staphylococcus epidermidis (incl. MRSE) Bactericidal

Staphylococcus haemolyticus Bactericidal
Staphylococcus hominis Bactericidal
Staphylococcus lugdunensis Bactericidal

Staphylococcus pasteuri Bactericidal

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Staphylococcus saprophyticus Bactericidal

Stenotrophomonas maltophilia Bactericidal

Streptococcus pneumoniae Bactericidal

Streptococcus pyogenes (incl. PRSP) Bactericidal

Streptococcus spp. Bactericidal

Strongyloides stercoralis Specific disinfectants effective against parasites are required

Т

Taenia solium Specific disinfectants effective against parasites are required

TBE virus Virucidal against enveloped viruses

Toxoplasma gondii Specific disinfectants effective against parasites are required

Treponema pallidum Bactericidal

Trichinella spiralis Specific disinfectants effective against parasites are required

Trichomonas vaginalis Specific disinfectants effective against parasites are required

Trichophyton spp. Fungicidal Trichosporon spp. Fungicidal

Trichuris trichiura Specific disinfectants effective against parasites are required

Trypanosoma brucei gambiense Specific disinfectants effective against parasites are required

Trypanosoma brucei rhodesiense Specific disinfectants effective against parasites are required

Trypanosoma cruzi Specific disinfectants effective against parasites are required

U

Usutu virus Virucidal against enveloped viruses

V

Vaccinia virus Virucidal against enveloped viruses

Varicella zoster virus Virucidal against enveloped viruses

Variola virus Virucidal against enveloped viruses

Vibrio cholerae Bactericidal

W

West Nile virus (WNV) Virucidal against enveloped viruses

Х

Υ

Yellow fever virus Virucidal against enveloped viruses

Yersinia enterocolitica Bactericidal

Yersinia pestis Bactericidal

Yersinia pseudotuberculosis Bactericidal

Z

Zika virus Virucidal against enveloped viruses

Is there a clinically relevant pathogen missing?

We are happy to add it. Please use the contact form to send us your suggestions.

About HARTMANN I

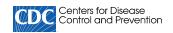
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Center for Disease Control and Prevention

"Common Settings of Norovirus Outbreaks"

https://www.cdc.gov/norovirus/trends-outbreaks/outbreaks.html



Norovirus

Common Settings of Norovirus Outbreaks

Most outbreaks of norovirus illness happen when infected people spread the virus to others through direct contact, such as by caring for them or sharing food or eating utensils with them. Food, water, and surfaces contaminated with norovirus can also cause outbreaks.

Norovirus outbreaks have been reported in many settings, some of the most commonly reported outbreak settings are listed below.

Healthcare Facilities

The most commonly reported setting for norovirus outbreaks in the United States and other industrialized countries is healthcare facilities, including long-term care facilities and hospitals. Over half of all norovirus outbreaks reported in the United States occur in long-term care facilities.

The virus can be introduced into healthcare facilities by infected patients, staff, visitors, or contaminated foods. Outbreaks in these settings can sometimes last months. Norovirus illnesses can be more severe, occasionally even deadly, in patients in hospitals or long-term care facilities compared with healthy people.

Restaurants and at Catered Events

Norovirus is the leading cause of outbreaks from contaminated food in the United States. About 50% of all outbreaks of food-related illness are caused by norovirus. Most of these outbreaks occur in food service settings like restaurants. Infected food workers are frequently the source of outbreaks in food-service settings, often by touching ready-to-eat foods, such as raw fruits and vegetables, with their bare hands before serving them. However, any food served raw or handled after being cooked can get contaminated with norovirus.

Norovirus outbreaks can also occur from food that is contaminated at the source or on the farm, such as oysters harvested from contaminated water, or fruit and vegetables sprayed with contaminated water in the field.

Foods that are commonly involved in norovirus outbreaks include:

- leafy greens (such as lettuce),
- · fresh fruits, and
- shellfish (such as oysters).

Schools and Child Care Centers

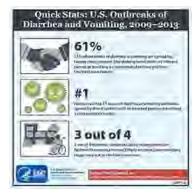
Norovirus outbreaks also frequently occur in schools, child care centers, colleges, and universities. Norovirus outbreaks on school and university campuses have even led to campus closures. Close quarters, shared spaces, and shared surfaces make it easy for norovirus to spread in schools.

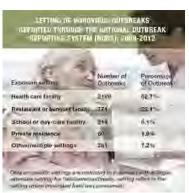
Cruise Ships

Definition of a Norovirus Outbreak

An outbreak of norovirus is defined as an occurrence of two or more similar illnesses resulting from a common exposure that is either suspected or laboratoryconfirmed to be caused by norovirus.

You can use the NORS Dashboard to learn about reports of outbreaks of foodborne. waterborne, and enteric (gastrointestinal) diseases spread by person-to-person contact, environmental contamination, animal contact, and more.





Cruise ships account for a small percentage (1%) of reported norovirus outbreaks overall. However, norovirus is most often the cause of outbreaks of diarrheal disease on cruise ships (over 90%). Because norovirus is the cause of most diarrheal outbreaks on cruise ships, and these outbreaks frequently get media attention, some people call norovirus the "cruise ship virus." Norovirus can be especially challenging to control on cruise ships because of the close living quarters, shared dining areas, and rapid turnover of passengers. When the ship docks, norovirus can be brought on board in contaminated food or water or by passengers who were infected while ashore. Repeated outbreaks on consecutive cruises may also result from infected crew or environmental contamination. This is because norovirus can persist on surfaces and is resistant to many common disinfectants.

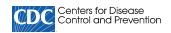
Related Pages
Norovirus in Healthcare Settings
Vital Signs on Preventing Norovirus Infection
CDC Estimates of Foodborne Illness in the United States
Tips for Healthy Cruising

Page last reviewed: June 1, 2018

Center for Disease Control and Prevention

"Burden of Norovirus Illness in the U.S."

https://www.cdc.gov/norovirus/trends-outbreaks/burden-US.html



Norovirus

Burden of Norovirus Illness in the U.S.

Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis (inflammation of the stomach and intestines) among people of all ages in the United States.

You can get norovirus illness at any time during the year

Most norovirus outbreaks in the United States happen from November to April. In years when there is a new strain of the virus, there can be 50% more norovirus illness.

Each year, on average in the United States, norovirus causes:

- 900 deaths, mostly among adults 65 and older
- 109,000 hospitalizations
- 465,000 emergency department visits, mostly in young children
- 2,270,000 outpatient clinic visits annually, mostly in young children
- 19 to 21 million cases of vomiting and diarrhea illnesses

109,000 hospitalizations 465,000 emergency department visits 2.27 million outpatient clinic visits 19 to 21 million total illnesses

Figure: Burden of Norovirus in the United States. Estimates of the annual number of illnesses and associated outcomes for norovirus disease in the U.S., across all age groups.

Norovirus is responsible for nearly 1 million pediatric medical care visits annually

Children under 5 and adults 85 and older are more likely to have an outpatient or emergency department visit than people who are other ages.

By 5 years of age:

- 1 in 110,000 will die from norovirus
- 1 in 160 will be hospitalized
- 1 in 40 will go to the emergency department
- 1 in 7 will go to an outpatient clinic

Norovirus outbreaks are common

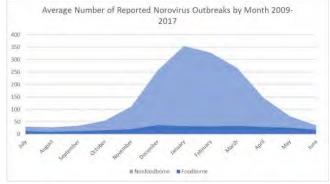
Each year, there are about 2,500 reported norovirus outbreaks in the United States. Norovirus outbreaks

Norovirus is the leading cause of foodborne illness in the United States.

It causes 58% of foodborne illnesses acquired in the United States. Each year, foodborne norovirus illness in the United States costs about \$2 billion, mainly due to lost productivity and healthcare expenses.

57/4200 Case 3:20-cv-01486-TWR-BLM Document 48-3 Filed 05/11/21 Page 10.1043 Page 3 of 100

occur throughout the year but are most common from November to April. Most outbreaks occur when infected people spread the virus to others through direct contact, such as by caring for them or sharing food or eating utensils with them. Learn about common settings of norovirus outbreaks.



Page last reviewed: May 8, 2020

NBC News

"5 Things You Didn't Know About Norovirus, the Nasty Stomach Flu"

https://www.nbcnews.com/health/health-news/5-things-you-didn-t-know-about-nasty-stomach-flu-n714241

Health news

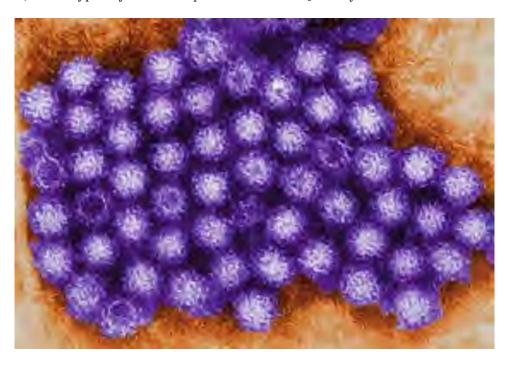
5 Things You Didn't Know About Norovirus, the Nasty Stomach Flu

Jan. 30, 2017, 11:28 AM PST / Updated Jan. 30, 2017, 11:28 AM PST

By Maggie Fox

It's flu season, and people in most states are being hit with a double whammy of influenza and norovirus – the winter vomiting virus also commonly known as the stomach flu.

The Centers for Disease Control and Prevention says 2017 is shaping up to look like <u>an average season</u> for both viruses, which typically come to a peak between late January and March.



A close-up of a norovirus that is causing food poisoning.CDC

Doctors often focus on warning patients about influenza, in part because it can be so deadly and in part because there are vaccines to prevent it. Norovirus is a nasty bug, but usually flies under the public health radar. Here are five things that may surprise you:

1. It mutates like real influenza does

While they are completely different viruses, norovirus and influenza are both RNA viruses, meaning they use RNA instead of DNA to replicate. That makes them both highly mutation-prone, which in turn makes it hard for the human immune system to defend against them. That's why you can get sick from norovirus year after year, says Dr. Aron Hall, CDC's norovirus expert.

"Every few years we see a new strain become predominant," Hall said. "Exposure to one strain of norovirus does not necessarily protect you against all strains."

2. It's hard to kill

Norovirus is enclosed by a structure known as a capsid. Alcohol cannot get through it, which is why alcohol-based hand sanitizers do not kill norovirus.

"It's resistant to many common disinfectants," Hall said. CDC recommends using bleach to kill it, including chlorine bleach or hydrogen peroxide. That's why health departments often require restaurants to use bleach to clean countertops and kitchen surfaces.

Related: Why Washing Your Hands Isn't Enough to Fight Norovirus

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It's also able to survive being dried out. "It can persist on surfaces for several days even at room temperature," Hall said. Soap and water can wash it away, but it takes really hot water to kill it. Hand-washed dishes are especially likely to carry the virus, and it can spread even in ordinary laundry, so if someone is sick, it's important to use very hot water and bleach to destroy virus that could be on any clothing, sheets or towels.



Norovirus tears across US; stomach bug causing widespread misery

JAN. 25, 201702:22

3. You can spread it after you get better

Just like influenza, norovirus is still being produced in your body after you get over symptoms from a bout. So people can spread it after they've returned to work.

Norovirus <u>spreads via the fecal-oral route</u>, so if people do not wash their hands very carefully after they have recovered from a bout of norovirus, they can spread it to others.

"Even once you feel better, you should still stay home at least one to two days," Hall advises.

4. One person can infect hundreds

Because it spreads even after people feel better, patients can and do go back out into the world while they are still infectious.

Combine a sticky, hard-to-kill virus with invisible spread by people who don't feel sick, and it makes a recipe for exponential spread.

Related: Vomiting Machine Shows Why Norovirus Spreads So Fast

Restaurant workers usually get little or no paid sick leave, so many workers come in sick, or too soon after they've recovered, and they can spread the virus to hundreds of customers. Food handlers, dishwashers, even staff who bus and clear tables, all can spread the germ.

"One ill food worker or even a worker who recovered has the potential to expose literally hundreds of people," Hall said.

And vomiting once can create an aerosol of virus that settles on surfaces all around.

In 2010, nine soccer players all got sick from a plastic shopping bag that got norovirus splashed on it.

The makes norovirus the most common cause of acute gastroenteritis – stomach upset – in the United States. It makes 21 million people sick every year in the United States – 70,000 on average get sick enough to go to the hospital. As many as 800 people die, mostly elderly patients who become dehydrated.

5. Several vaccines are in the works

While norovirus is nowhere near the killer that influenza is, several teams of researchers are nonetheless working on vaccines to prevent it. Globally, norovirus kills 200,000 people a year.

It's difficult in part because the virus mutates, and in part because the virus lives in the gut and it's hard to make vaccines that work there.

Drugmaker Takeda has a vaccine that's being tested in people now. At least one study has shown that about 20 percent of people of European origin have a genetic mutation that protects them from common norovirus strains, something that might help in development of better vaccines.



Maggie Fox

Maggie Fox is a senior writer for NBC News and TODAY, covering health policy, science, medical treatments and disease.



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Mayo Clinic Patient Care & Health Information

"Cryptosporidium Infection"

https://www.mayoclinic.org/diseases-conditions/ cryptosporidium/symptoms-causes/syc-20351870



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Cryptosporidium infection

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Overview **Print** Advertisement

Cryptosporidium infection (cryptosporidiosis) is an illness caused by tiny, one-celled cryptosporidium parasites. When cryptosporidia (krip-toe-spoe-RID-e-uh) enter your body, they travel to your small intestine and then burrow into the walls. Later, they're shed in your feces.

In most healthy people, a cryptosporidium infection produces a bout of watery diarrhea. The infection usually goes away within a week or two. If you have a compromised immune system, a cryptosporidium infection can become life-threatening without treatment.

You can help prevent a cryptosporidium infection by practicing good hygiene and avoiding swallowing water from pools, recreational water parks, lakes and streams.

Products & Services

Book: Mayo Clinic Family Health Book, 5th Edition

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Symptoms

The first sign of a control of the first sign of

- Watery diarrhea
- Dehydration
- Lack of appetite
- Weight loss
- · Stomach cramps or pain
- Fever
- Nausea
- Vomiting

Symptoms can last for up to two weeks, though they might come and go for up to a month, even in people with healthy immune systems. Some people with cryptosporidium infection have no symptoms.

When to see a doctor

Seek medical attention if you develop watery diarrhea that does not get better within a few days.

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Causes

Cryptosporidium infection begins when the one-celled cryptosporidium parasites get into your body through your mouth. Some strains of cryptosporidium can cause more serious disease.

These parasites then travel to your intestinal tract, where they settle into the walls of your intestines. Eventually, more cells are produced and are shed in massive quantities into your feces, where they are highly contagious.

You can become infected with cryptosporidia by touching anything that has come in contact with contaminated feces. You can get infected by:

- Drinking contaminated water that contains cryptosporidium parasites
- Swimming in contaminated water that contains cryptosporidium parasites and accidentally swallowing some of it

Page 1D. 4351 PRage 74 b 51240

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• Touching your hand to your mouth if your hand has been in contact with a contaminated surface, object, person or animal

If you have a compromised immune system from <u>HIV/AIDS</u>, you're more susceptible to illness from cryptosporidium parasites than is a person with a healthy immune system. People with <u>HIV/AIDS</u> can develop severe symptoms and a chronic, persistent form of disease that can be difficult to treat.

Hardy parasites

Cryptosporidium parasites are one of the more common causes of infectious diarrhea in humans. This parasite is difficult to to get rid of because it's resistant to many disinfectants and many filters don't remove it.

Cryptosporidia can survive for months at varying temperatures, though the parasite can be destroyed by boiling.

Risk factors

People who are at increased risk of developing cryptosporidiosis include:

- Children, particularly those wearing diapers, who attend child care centers
- · Parents of infected children
- Child care workers
- Animal handlers
- Those who engage in oral-to-anal sexual activity
- International travelers, especially those traveling to developing countries
- Backpackers, hikers and campers who drink untreated, unfiltered water
- Swimmers who swallow water in pools, lakes and rivers
- People who drink water from shallow, unprotected wells

Complications

Complications of cryptosporidium infection include:

Malnutrition resulting from poor absorption of nutrients from your intestinal tract

- \$\$\frac{224}{24}\$\frac{24}{24}\$\frac{24}{24}\$\frac{24}{21}\$\$ PagelD.4323 PRage ₹6.361.240
- Significant weight loss
- Inflammation of the passage between your liver, gallbladder and small intestine (bile duct)
- Inflammation of your gallbladder, liver or pancreas

Cryptosporidium infection isn't life-threatening. However, if you've had a transplant or if you have a weakened immune system, developing complications can be dangerous.

Prevention

Cryptosporidium infection is contagious, so take precautions to avoid spreading the parasite to other people. There's no vaccine to prevent a cryptosporidium infection.

To help prevent cryptosporidium infection:

- **Practice good hygiene.** Wash your hands for at least 20 seconds with soap and water after using the toilet and changing diapers, and before and after eating. Alcohol-based hand sanitizers don't kill the germs that cause cryptosporidium infection.
- Thoroughly wash with uncontaminated water all fruits and vegetables that you will eat raw, and avoid eating food you suspect could be contaminated. If you're traveling in a developing country, avoid uncooked foods.
- Purify drinking water if you have a weakened immune system or are traveling in an area with a high risk of infection. Methods include boiling
 — at least one minute at a rolling boil or filtering, although filtering might not be as effective as boiling.

Be sure to use a filter that meets the NSF International standard 53 or 58 requirements for cyst and oocyst reduction. You'll need a separate water filter for bacteria and viruses.

Avoid fecal exposure during sexual activity.

Always avoid swimming when you have diarrhea. If you know you've had a cryptosporidium infection, don't go swimming for at least two weeks after your symptoms go away because you can still be contagious.

Cases 6: 2020 Ac V-D48/04-07-WR-BBG 10 Document 22-3 Filed 05/24/21 PageID. 4354 PRage 7 14 fo 1240

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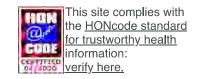
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Infection Control Today

"Outbreaks of Diarrhea Caused by Cryptosporidium Increased from 2009 Through 2017"

https://www.infectioncontroltoday.com/view/outbreaks-diarrhea-caused-cryptosporidium-increased-2009-through-2017



Outbreaks of Diarrhea Caused by Cryptosporidium Increased from 2009 Through 2017

June 28, 2019

Infectious Diseases & Conditions (/infectious-diseases-conditions), News (/news)

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Outbreaks of Cryptosporidium (Crypto) in the United States increased an average 13 percent each year from 2009 to 2017, according to a report published in CDC's Morbidity and Mortality Weekly Report.

Crypto, a parasite, is spread through the poop of infected humans or animals. People can get sick after they swallow the parasite in contaminated water or food or after contact with infected people or animals. Crypto is the leading cause of disease outbreaks in the United States linked to water, specifically outbreaks linked to pools or water playgrounds.

The report describes 444 outbreaks reported from 2009 through 2017, resulting in 7,465 people becoming sick, 287 hospitalizations, and one death.

- 35% of the outbreaks were linked to treated swimming water in places like pools and water playgrounds.
- 15% were linked to contact with cattle, particularly calves who were still nursing.
- 13% were linked to contact with infected people in childcare settings.
- 3% were linked to drinking raw (unpasteurized) milk or apple cider.

Improvements in testing patients for Crypto in recent years might be contributing to increased detection of outbreaks.

"Young children can get seriously sick and easily spread Crypto," says Michele Hlavsa, RN, MPH, chief of CDC's Healthy Swimming Program. They don't know how to use the toilet and wash their hands, or are just learning how. But we as parents can take steps to help keep our kids healthy in the water, around animals, and in childcare."

Crypto is protected by an outer shell that makes it tough to kill. For example, it can survive for days in chlorinated water in pools and water playgrounds or on surfaces disinfected with chlorine bleach. Crypto can easily cause outbreaks because it only takes a few germs to make someone sick, and there can be millions of Crypto germs in poop. Someone sick with Crypto can have diarrhea for up to three weeks.

Outbreaks caused by Crypto occur most commonly in the summer. Follow these effective steps to protect SER-179_{.076} yourself and others this summer and year-round:

- Do not swim or let kids swim in they have clarinear. Filled 05/24/21 PageID.4367 PRge & 0.761.240

—If eliagnosed with cryptosporidiosis, do not swim until two weeks after diarrhea completely stops.

(/mobile/login)

- Do not swallow the water you swim in.
- Keep kids sick with diarrhea at home and away from childcare.
- Wash your hands with soap and water after coming in contact with animals or anything in their environment, especially animal poop. Alcohol-based hand sanitizers do not work effectively on Crypto.
- Remove shoes worn in the animal environments (for example, in barns) before going inside your home.
- If you drink milk or apple cider, only buy if it has been pasteurized.

CryptoNet is the first U.S. national tracking system for a parasitic disease that is based on DNA fingerprinting. Crypto DNA fingerprinting can help determine how the parasite spreads and help detect and investigate outbreaks.

For more information on Crypto, visit https://www.cdc.gov/parasites/crypto/gen_info/prevention-general-public.html)

Source: CDC

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July 23, 2019

Getting up close - and a little dirty - with farm animals just might help us fend off illness, say researchers who've further demonstrated the benefits of early exposure to a wide variety of environmental bacteria.

EXHIBIT 15

Harvard Health Publishing, Harvard Medical School

Human Papilloma Virus (HPV)

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Human Papilloma Virus (HPV)

What Is It?

Published: July, 2019

Human papilloma virus (HPV) causes common warts, the small, white, beige or brown skin growths that can appear almost anywhere on the body and on the moist mucous membranes near the mouth, anus and genitals.

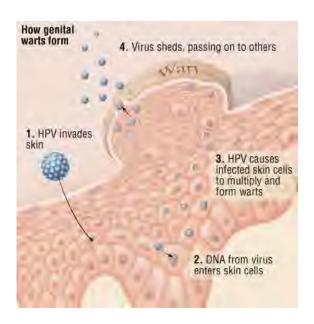
There are more than 150 different types of HPV, each with its own favorite skin surface to invade. Some cause the small, painless, rough-surfaced warts found on the fingers and face. Others cause the larger, more painful and flatter plantar warts that grow on the soles of the feet. More than 40 different types of HPV can infect the skin covering the sex organs, cervix and opening of the anus.

Genital HPV infections are very common. Up to 80 percent of sexually active adults will get an HPV infection of the genital area at some point in their lives. In most cases, these infections do not cause symptoms. They can cause genital warts

In a small number of women, certain HPV strains cause changes in the cervix that can become cancerous if not treated. HPV is also linked to cancers of the penis, vagina, anus, vulva, and also to mouth and throat cancers. HPV subtypes 16 and 18 are the causes of most cancers. HPV types 6 and 11 cause most cases of genital warts.

Human papilloma viruses usually are spread by direct skin contact, such as shaking the hand of someone who has a wart on their finger or having sexual intercourse with someone who has a genital HPV infection. Genital HPV infections can be spread by people with no symptoms, but the risk of infection is particularly high if you have intercourse with someone who has genital warts.

Less often, the viruses are carried on surfaces touched by someone who has warts, especially inside shoes that have been worn by someone with plantar warts. Once a person has been infected with an HPV, symptoms usually take three to four months to develop. However, in some cases, warts have developed as long as two years after contact with an infected person or contaminated surface.



Health experts estimate that common warts can be found on the hands of about one-fourth of all people in the United States, especially children. For some unknown reason, plantar warts are most common among teenagers and young adults.

Symploms: 2020-0-0-0486-6-WR-BGM Document 22-3 Filed 05/24/21 PageID.4390 PRgg & 20 to 1240

It is possible to have an HPV skin or genital infection without having symptoms. When an HPV infection does cause a wart, the appearance varies slightly depending on its location:

- Common skin warts These most often affect the hands, face, skin or scalp, and are especially common on sites of previous skin injury.

 They are small (about 6 millimeters or one-fourth of an inch), firm, painless, rounded growths that are whitish, pink, beige or brown. The wart surface may be smooth and pearly or rough like a cauliflower.
- **Flat warts** These are flat, white, beige or brown growths. They do not usually itch. They typically occur on the face, neck, chest, forearms, wrists or hands.
- Plantar warts These are thick, painful overgrowths of skin on the soles of the feet. They are often mistaken for simple calluses.
- **Genital warts** These usually appear as one to 10 pink, painless growths with a rough, cauliflower-like surface. In men, genital warts most commonly affect the tip of the penis, the opening of the urethra and the skin around the anus (especially in men who practice anal sex). In women, genital warts usually appear first at the posterior opening of the vagina and on the labia (the lip-like folds of skin around the vagina).



Cancer caused by HPV often causes no symptoms. When symptoms do occur, it depends on the location of the cancer:

- Cervical cancer Symptoms may include spotting after sex, abnormal vaginal bleeding, and/or pelvic pain.
- Oral cancer Symptoms may include a tongue or mouth sore that doesn't heal and/or a persistent discolored area in the mouth.
- **Anal cancer** Symptoms may include bleeding, itching and/or pain around the anus.

Diagnosis

Your doctor usually can diagnose warts by examining the area. By looking at the area, your doctor also can determine what treatment may be necessary. In general warts don't need to be biopsied. However, if your doctor is concerned that the changes could be cancerous, a skin biopsy may be needed. In a biopsy, a small piece of tissue is removed and examined under a microscope.

People with plantar warts may complain of pain on the bottom of their feet when walking. If you have possible plantar warts, your doctor will examine your affected foot. He or she will want to be sure there are no bone, joint or tendon problems that would explain the pain. Plantar warts might not be the actual cause of foot pain.

If you have possible genital warts, your doctor will ask about your sexual practices, including condom use and anal sex. Condoms help decrease the risk of getting infected with HPV and spreading it to partners. But the HPV might exist on areas not covered by a condom. If you engage in anal sex, your doctor will examine the area around and inside the anus for warts and other skin changes from HPV. If you engage in oral sex, your doctor can look for sores or discolored areas on your tongue and inside your mouth.

In women with genital warts, the doctor will do a pelvic and rectal exam. A Pap smear will be done to look for microscopic pre-cancer or early cancer of the cervix caused by HPV.

Your doctor may also do colposcopy to get a more detailed look at the surface of the cervix and vagina. This tube-like instrument has a light and lenses to give the doctor a magnified view of the cervix and nearby vaginal skin. A biopsy of abnormal cervical tissue may be necessary to look for cervical cancer.

DNA tests can identify the specific types of HPV infection in cells taken from a woman's cervix. The test helps to identify women who have the types of HPV infection associated with the development of cervical cancer. $SER-183_{0.080}$

Expected Duration

Many warts disappear on their own. This may take one or two years. Others last for longer periods.

Prevention

There are two FDA approved vaccines against human papillomavirus, Gardasil and Cervarix. Both vaccines are approved for females to help prevent cervical cancer.

The general recommendation is to vaccinate 11 and 12 year old girls with either vaccine. Girls as young as 9 years old may receive the vaccine. A complete series consists of three shots over 6 months. The same vaccine brand should be used for all three shots. Both vaccines are also available for older girls and young women up to age 26.

Only Gardasil is approved to prevent genital warts. It is available to males as well as females. The age range to receive the Gardasil for boys and men is age 9 to 26.

Ideally, girls and young women should get all three HPV doses prior to becoming sexually active.

Other than abstinence, there is no definite way to prevent all HPV infections. To lower your risk as much as possible, always use condoms and other barrier methods, such as dental dams for mouth-to-genital contact, for protection. If you or someone you know has a wart, avoid skin-to-skin contact with the wart.

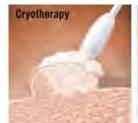
Treatment

Over-the-counter ointments, lotions and plasters are available to treat common skin warts. Do not use them for warts on the face, genitals or anus. They should not be used by people with diabetes, poor circulation or infected warts. Over-the-counter remedies use strong chemicals to slowly destroy the wart over a period of weeks or months. For faster and more lasting treatment, your doctor may try several procedures, including:

- · Removing the wart surgically
- Freezing the wart (cryosurgery)
- · Cauterizing the wart using electricity
- Applying stronger surface (topical) medications

A doctor should always examine warts on the face, genitals and anus. In some cases, the doctor will prescribe a medication such as podofilox (Condylox) or imiquimod (Aldara), which you can apply to the wart yourself. In other cases, you doctor will use an office-based treatment, such as:

- Surgical removal
- Cryotherapy (freezing)
- Application of strong medications, such as acids or podophyllum (Podofin, Podocon-25), to the skin
- · Interferon injections
- Laser therapy





Where & 200 Page 10 Pa

Make an appointment with your doctor whenever you suspect that you have a wart on your face, genitals or anus. If you have a wart on another area, you can try nonprescription treatments on your own, and see the doctor only if home treatment does not work.

If you are older than 45, talk to your doctor before trying to remove a common wart with an over-the-counter remedy. Your doctor may want to test for skin cancer.

Prognosis

The outlook varies. Many common warts disappear without treatment over 6 to 12 months. Others dissolve when an over-the-counter remedy is used for several weeks or months.

Of the office-based therapies, surgical removal of a wart gives the best immediate results, because the wart is cut away in one doctor's visit. Other forms of therapy require several office visits. After a wart has been removed, there is no guarantee that it will not come back, because it is difficult to be certain that HPV infection has been eliminated from the deeper layers of the infected skin. Some stubborn warts require several rounds of treatment before they go away for good.

Additional Info

Centers for Disease Control and Prevention

http://www.cdc.gov/

National Institute of Arthritis and Musculoskeletal and Skin Diseases

http://www.niams.nih.gov/

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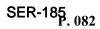


EXHIBIT 16

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"Warts"

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Warts

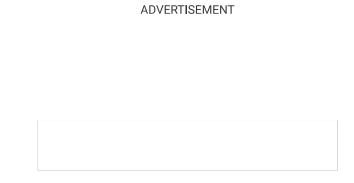
Warts are a type of skin infection caused by the human papillomavirus (HPV). The infection causes rough, skin-colored bumps to form on the skin. The virus is contagious. You can get warts from touching someone who has them. Warts most commonly appear on the hands, but they can also affect the feet, face, genitals and knees.

Symptoms and Causes Diagnosis and Tests Management and Treatment Outlook / Prognosis Prevention **Living With**

OVERVIEW

What are warts?

Warts are noncancerous (benign) rough bumps that forr develop when the human papillomavirus, or HPV, enters



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Who might get warts?

Children are more prone to warts because they get a lot of cuts. Still, anyone can get warts. People with autoimmune disease or weakened immune systems, including the elderly, are more susceptible to the virus that causes warts.

What are the types of warts?

Wart types vary depending on the affected body part. Types include:

- Hands: These warts are called common warts because they are the most common type.
- Face: Flat warts affect the face and forehead.
- Feet: Plantar warts appear on the soles of the feet. Th

in clusters.

- Genitals: Warts that form on the penis, vagina or rectum are called genital warts. These warts are a type of sexually transmitted infection. You get genital warts through sexual contact with an infected person.
- Periungual and subungual: These warts form under or around fingernails and toenails



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SYMPTOMS AND CAUSES

What causes warts and are they contagious?

When the human papillomavirus (HPV) enters a cut in the skin, it causes a skin infection that forms warts. Warts are very contagious. The virus can spread from person to person or from different parts of the body Let's Chat!

Direct contact with a wart.

- Touching something contaminated with the virus, such as towels, doorknobs and shower floors.
- Sexual intercourse (genital warts).
- Nail biting and cuticle picking.
- Shaving.

What are the symptoms of warts?

Warts vary in appearance. They may look:

- Dome-shaped.
- Flat.
- Rough.
- Skin-colored, brown, grey or black.



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DIAGNOSIS AND TESTS

How are warts diagnosed?

Your doctor can diagnose warts simply by looking at the bumps. Sometimes, your doctor may take a sample of the skin growth (biopsy) to test for HPV.

MANAGEMENT AND TREATMENT

How are warts managed or treated?

Warts often go away on their own after your immune system fights off the virus. Because warts can spread, cause pain and be unsightly, your doctor may recommend treatment. Options include:

- At-home wart removal: Over-the-counter (OTC) wart removal medications, such as Compound W®, contain salicylic acid. This chemical dissolves warts one layer at a time. These products come in liquid, gel and patch form. You may need to apply the medication every day for several months to get rid of the wart completely.
- Freezing: During a procedure called cryotherapy, your doctor applies liquid nitrogen to freeze the wart. After freezing, a blister forms. Eventually, the blister and wart peel off. You may need several treatments.
- **Immunotherapy:** For stubborn warts that don't respond to traditional treatments, immunotherapy helps your immune system fight the virus. This process involves a topical chemical, such as diphencyprone (DCP). DCP causes a mild allergic reaction that makes the wart go away.
- Laser treatment: Your doctor uses laser light to heat and destroy tiny blood vessels inside the wart. The process cuts off blood su
- Topical medicine: Your doctor may apply a liquid mixt

supply. You must return to your doctor's office in about a week to have the dead wart removed.

What are the complications of warts?

Most warts go away without any significant problems. Sometimes warts cause issues, such as:

- Cancer: HPV and genital warts are linked to several different cancers, including anal cancer, cervical cancer and throat (oropharyngeal) cancer. You can lower your risk of genital warts by getting the HPV vaccine and using condoms.
- **Disfigurement:** People with weakened immune systems may develop unappealing clusters of warts on the hands, face and body.
- Infection: Infections can occur if you pick or cut a wart. Breaks in the skin allow bacteria to enter.
- Pain: Most warts don't hurt. But plantar warts can grow inward into the foot and be painful to walk on. You may feel as if there's a pebble under the skin.

PREVENTION

How can I prevent warts?

There's really no way to prevent warts. However, you can lower your risk of picking up the virus or stop warts from spreading by taking these steps:

- Avoid shaving over a wart.
- Break the habit of biting your nails or picking at cuticle

- Don't share towels, washcloths, clothing, nail clippers, razors or other personal items.
- Don't touch another person's wart.
- Get the HPV vaccine and use condoms to prevent genital warts.
- Keep your feet dry to prevent the spread of plantar warts.
- Try not to scratch, cut or pick at a wart.
- Wear flip-flops or shoes when using a public locker room, pool area or showers.

OUTLOOK / PROGNOSIS

What is the outlook (prognosis) for people with warts?

Once you have the virus, there's no sure way to keep warts from returning. After treatment, warts can reappear at the same location or a different part of the body. But some people get rid of warts and never have one again.

LIVING WITH

When should I call my healthcare provider about warts?

You should call your provider if the wart:

Breaks open often, increasing the risk of infection or virus spread.

Causes embarrassment.

• Develops on the genitals or rectum (genital warts).

- Itches.
- Looks infected (red or pus-filled).
- Makes walking painful and difficult (plantar warts).

What questions should I ask my healthcare provider about warts?

If you or your child has warts, consider asking your provider:

- How did we get warts?
- How can we keep warts from spreading to other parts of our bodies?
- What steps can we take to prevent getting more warts?
- What steps can we take to ensure other family members don't get infected?
- What's the best treatment for the warts?
- Should I look out for any signs of complications?

Warts can be unsightly and embarrassing. The good news is that warts often go away on their own. They also respond well to treatment. The virus that causes warts spreads easily. Be sure to take the necessary steps to prevent warts from infecting other people or other parts of your body. Your doctor can recommend the best at-home or in-office treatment to get rid of warts.

SHARE

Last reviewed by a Cleveland Clinic medical professional on 04/26/2020.

References

EXHIBIT 17

Science Daily

"Popular Disinfectants Do Not Kill HPV"

https://www.sciencedaily.com/releases/2014/02/140212132944.htm



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Science News

from research organizations

Popular disinfectants do not kill HPV

Date: February 12, 2014

Source: Penn State

Summary: Commonly used disinfectants do not kill human papillomavirus (HPV) that makes possible non-sex-

ual transmission of the virus, thus creating a need for hospital policy changes, according to

researchers.

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FULL STORY

Commonly used disinfectants do not kill human papillomavirus (HPV) that makes possible non-sexual transmission of the virus, thus creating a need for hospital policy changes, according to researchers from Penn State College of Medicine and Brigham Young University.

"Because it is difficult to produce infectious HPV particles for research, little has been known about HPV susceptibility to disinfection," said Craig Meyers, Distinguished Professor of Microbiology and Immunology, Penn State College of Medicine.

Use of disinfectants on HPV in health care settings has been based on what works on other viruses or what is thought should be effective.

Meyers collaborated with Richard Robison, an expert in microbial disinfectants at Brigham Young University.

HPV is estimated to be among the most common sexually transmitted diseases and is linked to cervical cancers. For this study, researchers grew HPV16, a specific strain that is responsible for up to 60 percent of all HPV-associated cancers. They then used 11 common disinfectants on the virus.

These disinfectants included ones made of ethanol and isopropanol because these are common ingredients in surface disinfectants and hand sanitizers used in both public and health care settings. Study of these hand sanitizers is important because other research has shown high levels of HPV DNA on fingers of patients with current genital infections. While HPV is susceptible to certain disinfectants, including hypochlorite and peracetic acid, it is resistant to alcohol-based disinfectants.

"Chemical disinfectants in hand sanitizer are commonly used in the general population to prevent the spread of infectious diseases," Meyers said. "For flu or cold viruses they are very effective. But the data shows that they do nothing for preventing the spread of human papillomavirus."

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They also tested other common disinfectants, including glutaraldehyde, which is used for sterilization in medical and dental facilities. Results show that glutaraldehyde is not effective at inactivating the HPV virus.

Results were published in the *Journal of Antimicrobial Chemotherapy*.

Other research has suggested that HPV could be transmitted non-sexually. The current study shows that medical instruments considered sterile could pose a risk for transmission.

"Chemical disinfectants used in the hospitals and other healthcare settings have absolutely no effect on killing human papillomavirus," Meyers said. "So unless bleach or autoclaving is used in the hospital setting, human papillomavirus is not being killed and there is a potential spread of HPV through hospital acquired or instrument or tool infection."

Meyers said the results suggest a need for a change in disinfectant use policies.

Story Source:

Materials provided by Penn State. Original written by Matthew Solovey. Note: Content may be edited for style and length.

Journal Reference:

1. J. Meyers, E. Ryndock, M. J. Conway, C. Meyers, R. Robison. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. Journal of Antimicrobial Chemotherapy, 2014; DOI: 10.1093/jac/dku006

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Penn State, "Popular disinfectants do not kill HPV," ScienceDaily, ScienceDaily, 12 February 2014, <www.sciencedaily.com/releases/2014/02/140212132944.htm>.

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EXHIBIT 18

Center for Disease Control and Prevention

"What is C. diff?"

https://www.cdc.gov/cdiff/what-is.html



What is *C. diff*?

C. diff (also known as *Clostridioides difficile* or *C. difficile*) is a germ (bacterium) that causes severe diarrhea and colitis (an inflammation of the colon).

It's estimated to cause almost half a million infections in the United States each year.

About 1 in 6 patients who get *C. diff* will get it again in the subsequent 2-8 weeks.

One in 11 people over age 65 diagnosed with a healthcare-associated *C. diff* infection die within one month.

Risk Factors for C. diff

C. diff can infect anyone. Most cases of *C. diff* occur when you've been taking antibiotics or not long after you've finished taking antibiotics.

There are other risk factors:

- Being 65 or older
- Recent stay at a hospital or nursing home
- A weakened immune system, such as people with HIV/AIDS, cancer, or organ transplant patients taking immunosuppressive drugs
- Previous infection with *C. diff* or known exposure to the germs



Symptoms of *C. diff*

Symptoms might develop within a few days after you begin taking antibiotics.

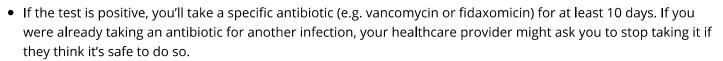
- Severe diarrhea
- Fever
- Stomach tenderness or pain
- Loss of appetite
- Nausea



What if I have symptoms?

If you have been taking antibiotics recently and have symptoms of *C. diff*, you should see a healthcare professional.

- Developing diarrhea is fairly common while on, or after taking, antibiotics, but in only a few cases will that diarrhea be caused by *C. diff.* If your diarrhea is severe, do not delay getting medical care.
- Your healthcare professional will review your symptoms and order a lab test of a stool (poop) sample.



• Your healthcare professional might decide to admit you to the hospital, in which case your healthcare providers will use certain precautions, such as wearing gowns and gloves, to prevent the spread of *C. diff* to themselves and to other patients.



Is C. diff contagious?

Yes. To keep from spreading *C. diff* to others:

- Wash hands with soap and water every time you use the bathroom and always before you eat.
- Try to use a separate bathroom if you have diarrhea.
- Take showers and wash with soap.



Can I get C. diff again?

Some people get *C. diff* over and over again.

- One in 6 people who've had *C. diff* will get it again in the subsequent 2-8 weeks.
- If you start having symptoms again, seek medical care.
- For those with repeat infections, innovative treatments, including fecal microbiota transplants, have shown promising results (see the "Life After *C. diff*" page).



Fact Sheet About C. diff

Page last reviewed: November 16, 2020

Content source: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP)

https://www.cdc.gov/cdiff/what-is.html

EXHIBIT 19

Mayo Clinic

"C. difficile infection"

mayoclinic.org/diseases-conditions/c-difficile/symptoms-causes/syc-20351691



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Clostridium difficile (klos-TRID-e-um dif-uh-SEEL), also known as Clostridioides difficile and often referred to as C. difficile or C. diff, is a bacterium that can cause symptoms ranging from diarrhea to life-threatening inflammation of the colon.

Illness from C. difficile most commonly affects older adults in hospitals or in long-term care facilities and typically occurs after use of antibiotic medications. However, studies show increasing rates of C. difficile infection among people traditionally not considered to be at high risk, such as young and healthy individuals who haven't used antibiotics and who haven't been in a health care facility.

Each year in the United States, about a half million people get sick from C. difficile, and in recent years, C. difficile infections have become more frequent, severe and difficult to treat. Recurrent C. difficile infections also are on the rise.

C. difficile infection care at Mayo Clinic

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Some people carry the bacterium C. difficile in their intestines but never become sick, though rarely may still spread the infection. Signs and symptoms usually develop within five to 10 days after starting a course of antibiotics, but may occur as soon as the first day or up to two months later.

Mild to moderate infection

The most common signs and symptoms of mild to moderate C. difficile infection are:

- Watery diarrhea three or more times a day for two or more days
- Mild abdominal cramping and tenderness

Severe infection

People who have a severe C. difficile infection tend to become dehydrated and may need to be hospitalized. C. difficile can cause the colon to become inflamed and sometimes form patches of raw tissue that can bleed or produce pus. Signs and symptoms of severe infection include:

- Watery diarrhea 10 to 15 times a day
- Abdominal cramping and pain, which may be severe
- Rapid heart rate
- Fever
- Blood or pus in the stool
- Nausea
- Dehydration
- Loss of appetite
- Weight loss
- Swollen abdomen
- · Kidney failure
- · Increased white blood cell count

Severe C. difficile infection may also cause severe intestinal inflammation, enlargement of the colon (also called toxic megacolon) and sepsis. People who have these conditions are often admitted to the intensive care unit.

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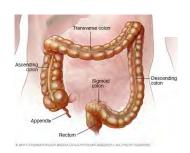
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- Three or more watery stools a day
- · Symptoms lasting more than two days
- A new fever
- · Severe abdominal pain or cramping
- Blood in your stool

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Causes

C. difficile bacteria are found throughout the environment — in soil, air, water, human and animal feces, and food products, such as processed meats. A small number of healthy people naturally carry the bacteria in their large intestines and don't have ill effects from the infection.



Colon and rectum

Spores from C. difficile bacteria are passed in feces and spread to food, surfaces and objects when people who are infected don't wash their hands thoroughly. These spores can persist in a room for weeks or months. If you touch a surface contaminated with C. difficile spores, you may then unknowingly swallow the bacteria.

Once established, C. difficile can produce toxins that attack the lining of the intestine. The toxins destroy cells, produce patches (plaques) of inflammatory cells and decaying cellular debris inside the colon, and cause watery diarrhea.

Emergence of a new strain

An aggressive strain of C. difficile has emerged that produces far more toxins than other strains do. The new strain may be more resistant to certain medications and has shown up in people who haven't been in the hospital or taken antibiotics. This strain of C. difficile has caused several outbreaks of illness since 2000.

Although people who have no known risk factors have gotten sick from C. difficile, certain factors increase the risk.

Taking antibiotics or other medications

Your intestines contain about 100 trillion bacterial cells and up to 2,000 different kinds of bacteria, many of which help protect your body from infection. When you take an antibiotic to treat an infection, these drugs tend to destroy some of the normal, helpful bacteria in addition to the bacteria causing the infection. Without enough healthy bacteria to keep it in check, C. difficile can quickly grow out of control. The antibiotics that most often lead to C. difficile infections include:

- Fluoroquinolones
- Cephalosporins
- Penicillins
- Clindamycin

Proton pump inhibitors, a type of medicine used to reduce stomach acid, also may increase your risk of C. difficile infection.

Staying in a health care facility

The majority of C. difficile infections occur in people who are or who have recently been in a health care setting — including hospitals, nursing homes and long-term care facilities — where germs spread easily, antibiotic use is common and people are especially vulnerable to infection. In hospitals and nursing homes, C. difficile spreads mainly on hands from person to person, but also on cart handles, bedrails, bedside tables, toilets, sinks, stethoscopes, thermometers — and even telephones and remote controls.

Having a serious illness or medical procedure

If you have a serious illness, such as inflammatory bowel disease or colorectal cancer, or a weakened immune system as a result of a medical condition or treatment (such as chemotherapy), you're more susceptible to a C. difficile infection. Your risk of C. difficile infection is also greater if you've had abdominal surgery or a gastrointestinal procedure.

Other risk factors

Having one C. difficile infection increases your chance of having another one, and the risk continues to increase with each infection.

Complications

Complications of C. difficile infections include:

- Dehydration. Severe diarrhea can lead to a significant loss of fluids and electrolytes. This makes it difficult for your body to function normally and can cause blood pressure to drop to dangerously low levels.
- **Kidney failure.** In some cases, dehydration can occur so quickly that kidney function rapidly deteriorates (kidney failure).
- **Toxic megacolon.** In this rare condition, your colon is unable to expel gas and stool, causing it to become greatly distended (megacolon). Left untreated, your colon may rupture, causing bacteria from the colon to enter your abdominal cavity. An enlarged or ruptured colon requires emergency surgery and may be fatal.
- A hole in your large intestine (bowel perforation). This is rare and
 results from extensive damage to the lining of your large intestine or
 after toxic megacolon. A perforated bowel can spill bacteria from the
 intestine into your abdominal cavity, leading to a life-threatening
 infection (peritonitis).
- Death. Even mild to moderate C. difficile infections can quickly progress to fatal disease if not treated promptly.

Prevention

To help prevent the spread of C. difficile, hospitals and other health care facilities follow strict infection-control guidelines. If you have a friend or family member in a hospital or nursing home, don't be afraid to remind caregivers to follow the recommended precautions.

Preventive measures include:

Avoid unnecessary use of antibiotics. Antibiotics are sometimes
prescribed for viral illnesses that aren't helped by these drugs. Take a
wait-and-see approach with simple illnesses. If you do need an
antibiotic, ask your doctor to prescribe one that has a narrow range and
that you take for the shortest time possible.

- Hand-Washing-Pilestin Carle Washer-Spicial processing of the Carle 1972 Processing the
- Contact precautions. People who are hospitalized with C. difficile
 have a private room or share a room with someone who has the same
 illness. Hospital staff and visitors wear disposable gloves and isolation
 gowns while in the room.
- Thorough cleaning. In any health care setting, all surfaces should be carefully disinfected with a product that contains chlorine bleach. C. difficile spores can survive exposure to routine cleaning products that don't contain bleach.

By Mayo Clinic Staff

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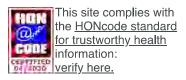
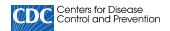


EXHIBIT 20

Center for Disease Control and Prevention

"Prevent the Spread of C. diff"

https://www.cdc.gov/cdiff/prevent.html



Clostridioides difficile (C. diff)

Prevent the Spread of *C. diff*

Information for Patients

C. diff germs are carried from person to person in poop.

If someone with *C. diff* (or caring for someone with *C. diff*) doesn't clean their hands with soap and water after using the bathroom, they can spread the germs to everything they touch.

And if someone with *C. diff* can't take a shower with soap and water, they can end up with *C. diff* germs on their skin.

Then, when someone else touches the skin of that person, or the surfaces that person touched, they can pick up the germs on their hands.

C. diff germs are so small relative to our size that if you were the size of the state of California, a germ would be the size of a baseball home plate. There's no way you can see *C. diff* germs on your hands, but that doesn't mean they're not there.

Washing with soap and water is the only way to prevent the spread from person to person.

Remember: you can come in contact with *C. diff* germs—and even carry them on, or in, your body—and not get sick. But that doesn't mean you can't infect others.



How long can C. diff germs live?

When *C. diff* germs are outside the body, they become spores. These spores are an inactive form of the germ and have a protective coating allowing them to live for months or sometimes years on surfaces and in the soil.

The germs become active again when these spores are swallowed and reach the intestines.

Healthy people will often not be infected even if the spores reach their intestines, but if your immune system is weakened or you've recently taken antibiotics, you could get sick.

How do I make sure I don't spread C. diff?

In a healthcare setting

Make sure all doctors, nurses, and other healthcare providers clean their hands before and after caring for you. If you don't see your providers clean their hands, ask them to do so.

While caring for you and other patients with *C. diff*, doctors, nurses and other healthcare providers will use certain precautions, such as gowns and gloves, to prevent the spread of *C. diff* to themselves and to other patients.

If you're in the hospital, wash your hands with soap and water every time you use the bathroom and always before you eat. Remind relatives and friends taking care of you to do the same.

At home SER-212

Wash your hands with soap and water every time you use the bathroom and always before you eat. Remind relatives and friends taking care of you to do the same.

Try to use a separate bathroom if you have diarrhea. If you can't, be sure the bathroom is well cleaned before others use it.

Take showers and wash with soap to remove any C. diff germs you could be carrying on your body.

How do I kill C. diff germs at home?

Finding *C. diff* germs in the home is not unusual, even when no one in the home has been ill with *C. diff*. Most healthy adults who come in contact with *C. diff* in the home won't get sick.

Hospitals use special cleaning products to kill *C. diff*, but you can make a cleaner at home. Mix 1 part bleach to 9 parts water.

bised:

Surfaces

When you're cleaning, focus on items that are touched by hands:

- doorknobs
- electronics (be careful because bleach can damage many electronics and plastics)
- refrigerator handles
- shared cups
- toilet flushers and toilet seats

Laundry

If someone in your house has C. diff, wash items they touch before others use them. These include but are not limited to:

- bed linens
- towels
- household linens
- · clothing, especially underwear

If these things have visible poop, rinse them well before washing.

Then launder in a washer and dryer, using the hottest water that is safe for those items. Use chlorine bleach if the items can be safely washed with it.

Wash your hands with soap and water after you handle the dirty laundry.

It's OK to take clothes to a dry cleaner that were worn by a patient infected with *C. diff.* However, dry cleaning isn't as effective as other methods at killing the spores. So this option should be used only for clothes that can't be machine-washed.

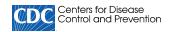
Page last reviewed: November 4, 2019

EXHIBIT 21

Center for Disease Control and Prevention

"Show Me the Science – When & How to Use Hand Sanitizer in Community Settings"

https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html



Handwashing: Clean Hands Save Lives

Show Me the Science – When & How to Use Hand Sanitizer in Community Settings



During the Coronavirus Disease 19 (COVID-19) pandemic, keeping hands clean is especially important to help prevent the virus from spreading.



Find answers to frequent questions about hand hygiene on the Hand Hygiene FAQs page.

CDC recommends washing hands with soap and water whenever possible because handwashing reduces the amounts of all types of germs and chemicals on hands. But if soap and water are not available, using a hand sanitizer with at least 60% alcohol can help you avoid getting sick and spreading germs to others. The guidance for effective handwashing and use of hand sanitizer in community settings was developed based on data from a number of studies.

Note: For hand hygiene guidance in healthcare settings, please visit the Clean Hands Count webpage.

Alcohol-based hand sanitizers can quickly reduce the number of microbes on hands in some situations, but sanitizers do *not* eliminate all types of germs.

Why? Soap and water are more effective than hand sanitizers at removing certain kinds of germs, like Cryptosporidium, norovirus, and Clostridium difficile¹⁻⁵. Although alcohol-based hand sanitizers can inactivate many types of microbes very effectively when used correctly 1-15, people may not use a large enough volume of the sanitizers or may wipe it off before it has dried ¹⁴.

Hand sanitizers may not be as effective when hands are visibly dirty or greasy.

Why? Many studies show that hand sanitizers work well in clinical settings like hospitals, where hands come into contact with germs but generally are not heavily soiled or greasy 16. Some data also show that hand sanitizers may work well against certain types of germs on slightly soiled hands ^{17,18}. However, hands may become very greasy or soiled in community settings, such as after people handle food, play sports, work in the garden, or go camping or fishing. When hands are heavily soiled or greasy, hand sanitizers may not work well ^{3,7,16}. Handwashing with soap and water is recommended in such circumstances.

Hand sanitizers might not remove harmful chemicals, like pesticides and heavy metals, from hands.

Why? Although few studies have been conducted, hand sanitizers probably cannot remove or inactivate many types of harmful chemicals. In one study, people who reported using hand sanitizer to clean hands had increased levels of pesticides in their bodies 19. If hands have touched harmful chemicals, wash carefully with soap and water (or as directed by a poison control center).

If soap and water are not available, use an alcohol-based hand sanitizer that contains at least 60% alcohol.

SER-215

Case 3:20-cv-01486-TWR-BLM Document 48-3 Filed 05/11/21 PageID.1093 Page 53 of 100 Wny7 Many studies have found that sanitizers with an alcohol concentration between 60-95% are more effective at killing

germs than those with a lower alcohol concentration or non-alcohol-based hand sanitizers ^{16,20}. Hand sanitizers without 60-95% alcohol 1) may not work equally well for many types of germs; and 2) merely reduce the growth of germs rather than kill them outright.

When using hand sanitizer, apply the product to the palm of one hand (read the label to learn the correct amount) and rub the product all over the surfaces of your hands until your hands are dry.

Why? The steps for hand sanitizer use are based on a simplified procedure recommended by CDC ²¹. Instructing people to cover all surfaces of both hands with hand sanitizer has been found to provide similar disinfection effectiveness as providing detailed steps for rubbing-in hand sanitizer ²².

Swallowing alcohol-based hand sanitizers can cause alcohol poisoning.

Why? Ethyl alcohol (ethanol)-based hand sanitizers are safe when used as directed, ²³ but they can cause alcohol poisoning if a person swallows more than a couple of mouthfuls ²⁴.

From 2011 – 2015, U.S. poison control centers received nearly 85,000 calls about hand sanitizer exposures among children ²⁵. Children may be particularly likely to swallow hand sanitizers that are scented, brightly colored, or attractively packaged. Hand sanitizers should be stored out of the reach of young children and should be used with adult supervision. Child-resistant caps could also help reduce hand sanitizer-related poisonings among young children ²⁴. Older children and adults might purposefully swallow hand sanitizers to become drunk ²⁶.

References +

Page last reviewed: September 10, 2020

EXHIBIT 22

Penn Medicine, Health and Wellness

"How to Use Hand Sanitizer"

https://www.pennmedicine.org/updates/blogs/health-and-wellness/2020/august/how-to-use-hand-sanitizer

Penn Medicine

Health and Wellness

How to Use Hand Sanitizer

August 21, 2020

TOPICS: <u>Coronavirus (COVID19)</u> <u>General Health Information</u>

HAND SANITIZER

DO'S and DON'TS



Use hand sanitizer if you can't use soap and water.

Pick a sanitizer with at least 60% alcohol.

Coat your palms and fingers.

Rub in thoroughly for 20 seconds.

Store in a cool, dry location.

Keep out of children's reach.

Dispose of expired sanitizer.



Make your own.

Wipe or rinse it off.

Use in place of regular hand washing.

Touch your eyes, nose or mouth after use.

Store in your car.

Handle fire/flames after use.

By now, you've seen guidelines for washing your hands with soap and water. Scrub for 20 seconds. Pay attention to your thumbs and fingernails. Don't touch the faucet once your hands are clean, and use a clean towel.

The emphasis on using regular soap and water is no accident. It's the best way to get rid of germs of all kinds, and when done correctly, it's effective against the novel coronavirus that causes COVID-19.

You should wash your hands regularly, especially after spending time in public, before preparing food or eating, and after you sneeze, cough, or blow your nose.

But you may not always have access to hand soap and a sink. In a pinch, hand sanitizer can be a convenient alternative.

To use hand sanitizer effectively against the coronavirus, you need the right type, amount, and application method.

Choose the Right Hand Sanitizer

Because the COVID-19 pandemic has made some name-brand sanitizers harder to find, you may see new brands on store shelves. Before putting a bottle in your cart, read the product label.

You should choose an alcohol-based hand sanitizer that contains at least 60 percent alcohol.

The Food and Drug Administration has also advised against hand sanitizers that contain methanol, a substance that can be toxic when rubbed into skin. Some hand sanitizers are labeled as containing ethanol or ethyl alcohol but actually contain methanol. You can use the FDA's searchable database to make sure your hand sanitizer brand isn't one of the offenders.

In addition, the FDA has not approved any hand sanitizers, so steer clear of brands labeled "FDA-approved."

Homemade hand sanitizer is not recommended. If it's not made correctly, hand sanitizer can be ineffective or even harmful to your skin.

Use the Right Amount of Hand Sanitizer

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One mistake many people make is using too little hand sanitizer, especially if your dispenser doesn't provide enough in one squeeze.

The World Health Organization recommends applying a "coin-sized amount" of gel. In other words, you need enough hand sanitizer to cover both sides of your hands and between your fingers – just as you do with hand soap.

Apply Hand Sanitizer Correctly

After applying the gel, rub it in thoroughly. Pay attention to the back of your hands, thumbs, and between your fingers. Like washing your hands at a sink, this process should take about 20 seconds.

When you're done, your hands should be dry. Don't wipe or rinse off the gel.

Storing Hand Sanitizer

Chances are, you're using more hand sanitizer these days than ever before. But sanitizer does have a shelf life. Its alcohol content gradually drops as the expiration date approaches. If you have expired hand sanitizer, dispose of it and get a new bottle.

Store your hand sanitizer in a cool, dry location. Avoid direct sunlight and repeated exposure to heat.

When you return home, bring your hand sanitizer inside instead of tossing it into the glovebox or a cup holder. While there's little risk of combustion, extreme heat can speed up alcohol evaporation—especially if air gets inside the bottle.

Hand Sanitizer Safety

Keep these safety tips in mind to avoid irritation or poisoning:

- Never ingest hand sanitizer.
- Keep hand sanitizer out of the reach of children and supervise their use.
- Don't touch your eyes, nose, or mouth immediately after use.
- Don't handle fire or open flames immediately after use.

Get the latest COVID-19 information

Get more hand washing tips

Contact us

EXHIBIT 23

Journal of Medical Virology

Study regarding Single Treatment With Ethanol Hand Rub Is Ineffective Against Human Rhinovirus—Hand Washing With Soap and Water Removes the Virus Efficiently

COVID-19 is an emerging, rapidly evolving situation.

Get the latest public health information from CDC: https://www.coronavirus.gov.

Get the latest research from NIH: https://www.nih.gov/coronavirus.

FULL TEXT LINKS



J Med Virol. 2012 Mar;84(3):543-7. doi: 10.1002/jmv.23222.

Single Treatment With Ethanol Hand Rub Is Ineffective Against Human Rhinovirus--Hand Washing With Soap and Water Removes the Virus Efficiently

Carita Savolainen-Kopra ¹, Terttu Korpela, Marja-Leena Simonen-Tikka, Ali Amiryousefi, Thedi Ziegler, Merja Roivainen, Tapani Hovi

Affiliations

PMID: 22246844 DOI: 10.1002/jmv.23222

Abstract

Ethanol-containing hand rubs are used frequently as a substitute for hand washing with water and soap. However, not all viruses are inactivated by a short term rubbing with alcohol. The capacity of a single round of instructed and controlled hand cleaning with water and soap or ethanol-containing hand rub, respectively, was tested for removal of human rhinovirus administered onto the skin of healthy volunteers on the back of the hands. Hand washing with soap and water appeared to be much more efficient for removing rhinoviruses from skin than rubbing hands with an ethanol-containing disinfectant. After washing with soap and water the virus was detected in 3/9 (33.3%) test persons from the left hand and 1/9 (11.1%) cases from the right hand, whereas the virus was detected invariably by real-time RT-PCR from both hands after cleaning with alcohol hand rub (P-value <0.01). Both substances evaluated clinically were also tested in vitro for virucidal efficacy against Human rhinovirus2 (HRV2) using a standardized assay. Both tested substances were poor within the contact time used in the hand-cleaning test. In conclusion, thorough and conventional hand washing with water and soap can clean efficiently hands contaminated with the virus responsible for an extensive share of common cold episodes.

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Wiley

Miscellaneous

Hazardous Substances Data Bank

SER-224 P. 121

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2 4 <u>5</u> 6 7 8 9 13 14 15 16 17 18 19 21 <u>23</u> <u>24</u> <u> 26</u>

28

I. INTRODUCTION AND FACTUAL BACKGROUND

A. Introduction

- 1. This putative class action seeks to hold Defendant Vi-Jon, LLC ("Defendant")¹ responsible for misstatements made on the labels of its hand sanitizing products (defined below as the "Products").
- 2. On the front-facing, principal display panel, Defendant states that the Products "kill[] 99.99% of germs" or "kill[] more than 99.99% of germs" (the "Representation" or "Front Panel Representation").
 - 3. The Front Panel Representation is followed by an asterisk.
- 4. Following an asterisk on the back panel of the Products is the statement: "Effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 15 seconds" or "Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds." (The "Back Panel Statement" or, collectively with the "Front Panel Representation", the "Representations").²

Defendant's Front Panel Representation is False and Misleading

- 5. Defendant's Front Panel Representation is false and misleading because the Products do not kill 99.99% of germs.
 - 6. Germs is a commonly understood term as an organism that causes disease.
- 7. Defendant's Products do not kill 99.99% or more than 99.99% of disease-causing organisms.
- 8. According to a compendium of disease causing agents provided by the BODE SCIENCE CENTER, which specializes in infection prevention, there are approximately 204 clinically relevant pathogens.
- ¹ Defendant Vi-Jon LLC was formerly named as Vi-Jon, Inc. In or around fall of 2020, Defendant became a Limited Liability Company.
- ² The label Representations on the Products are substantially the same, irrespective of the "more than" language included on certain of the Products. In addition, if the 99.99% language is false and/or misleading, the more than 99.99% language is also necessarily false and/or misleading.

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Never has it been demonstrated more saliently that consumers rely on hand sanitizers to "kill germs" on their hands in order to protect themselves from infection. And never has it been more important that manufacturers disseminate accurate and truthful information to the consuming public about the limitations of those products to "kill germs" or, more precisely, denature certain microbes that can cause infection.⁴

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1	9. Of those 204 pathogens, Defendant's Products are ineffective or	
<u>1</u> <u>2</u>	substantially ineffective against approximately 54 pathogens, or approximately 26% of	
<u>3</u>	the listed disease-causing agents.	
<u>4</u>	10. A substantial number of the pathogens identified by the BODE SCIENCE	
<u>5</u>	CENTER are transmitted by hands.	
<u>6</u>	11. A substantial number of the pathogens identified by the BODE SCIENCE	
<u>7</u>	CENTER are not killed by the Products.	
<u>8</u>	12. The number of pathogens against which the Products are ineffective alone	
9	demonstrates the inaccuracy of Defendant's Representations.	
<u>10</u>	13. The limitation of the Products' ability to "kill germs" falls into three general	
<u>11</u>	categories.	
<u>12</u>	14. First, the Products contain ethyl alcohol as the active ingredient, which is	
<u>13</u>	unable to "kill" certain pathogens such as: non-enveloped viruses, which are composed	
<u>14</u>	of dense genetic material that is difficult to disrupt; protozoa pathogens, which are	
<u>15</u>	protected by an outer shell that cannot be penetrated by ethyl alcohol; and certain	
<u>16</u>	<u>bacterial spores.</u>	
<u>17</u>	15. Each category of pathogens against which the Products are ineffective	
<u>18</u>	contains numerous types of disease causing organisms.	
<u>19</u>	16. The categories of pathogens against which the Products are ineffective	
<u>20</u>	account for millions of cases of infection in the United States each year.	
<u>21</u>	17. Second, ethyl alcohol evaporates quickly; the Products are less effective or	
<u>22</u>	wholly ineffective based on the length of time that the sanitizer remains on hands.	
<u>23</u>	18. Third, the Products may be wholly ineffective depending on the condition	
<u>24</u>	of the hands to which they are applied.	
<u>25</u>	19. Hands that are dirty, grimy, or greasy may reduce or eliminate the efficacy	
<u>26</u>	of the Products.	Deleted: FIRST
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	SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS	

Deleted: <object> Defendant's Back Panel Statement is Also False and Misleading The Back Panel Statement does not cure the false and misleading Front Panel Representation. 4 Moreover, the Back Panel Statement is itself false and misleading because Defendant's Products are ineffective against "many common harmful germs and 5 bacteria".3 6 7 22. Defendant's Products are ineffective against, for example, the "common 8 harmful germ" norovirus, which causes about 50% of all outbreaks of food-related 9 illness in the United States. 23. Norovirus is transmitted by hands, including where infected food workers handle food and transfer the virus. 12 24. Defendant's Products are also ineffective against the "common harmful germ" cryptosporidium, which is one of the common causes of diarrhea in humans. Cryptosporidium can be transmitted where a person's hands are 14 contaminated with the parasite and that person touches and contaminates a surface. Defendant's Products are also ineffective against the "common harmful 16 17 germ" human papillomavirus, or HPV. According to Harvard Health Publishing of the Harvard Medical School, 18 19 there are more than 150 types of HPV. 20 Many types of HPV are responsible for "common" warts on the hands, face and skin, and are not transmitted sexually but are transmitted by hand to hand contact or by touching something that an infected individual has touched. <u>23</u> Health experts estimate that HPV causes common warts on the hands of about one-fourth of all people in the United States. See Harvard Health Publishing <u>24</u> (discussed in detail below in Section IV.B.3 below). <u>26</u> Deleted: FIRST Formatted: Font: 14 nt Specific information about certain pathogens, including evidence and cited exhibits demonstrating that they are: common, transmitted by hands, and not killed by the Deleted: 28 Formatted: Left Products, is included in Section IV. Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT____20-CV-1446-JM-BGS

Deleted: <object> 30. Defendant's Products are also ineffective against the "common harmful germ" clostridioides difficile or C. diff. C. diff. causes about 500,000 cases of illness per year. 4 Individuals infected with C. diff can spread the germs to everything they <u>5</u> touch. 33. Defendant's Back Panel Statement is additionally false and misleading 6 because the Products do not eliminate "99.99% of many common harmful germs and 7 bacteria in as little as 15 seconds" (emphasis added). 8 9 34. In its guidance regarding hand sanitizer use, the Center for Disease Control and Prevention ("CDC") states that hand sanitizer should remain on hands for "around 20 seconds." https://www.cdc.gov/handwashing/hand-sanitizer-use.html, attached as Exh. 1. In addition, as stated, the Products may be ineffective against germs, including "common harmful germs", irrespective of the amount of time they remain on 14 15 hands where they are not rubbed all over the hands, or where the hands to which they are applied are dirty, grimy or greasy. 16 17 Defendant Omits Material Information In labeling its Products, Defendant omits material information concerning 18 19 the limitations of the Products to kill germs. 20 Defendant's omissions are material to consumers. 21 Reasonable consumers deserve and desire to know when the Products will "kill germs" and when they will not. <u>22</u> If Defendant accurately labeled its Products, consumers would know when <u>23</u> they should seek other sanitization measures, such as washing their hands with soap and <u>24</u> water. <u> 26</u> Defendant's Representations are Misleading to Reasonable Consumers Deleted: FIRST Formatted: Font: 14 nt <u>27</u> Plaintiff and reasonable consumers rely and have relied on the Products for Deleted: 28 their health and safety. Formatted: Left Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

particular purpose of sanitizing hands and killing germs. 4 in purchasing the Products. Defendant's Representations and omissions. 6 8 purchase price of the Products. 9 Products, or would have paid less for them. 13 46. 14 Walgreen Co. (collectively the "Products").4 18 Products. <u>19</u> 48. Products kill 99.99% of germs.⁵ 24 <u> 26</u>

Plaintiff and reasonable consumers have purchased the Products for the

- Plaintiff and reasonable consumers relied on Defendant's Representations
- Plaintiff and reasonable consumers were misled and deceived by
- Plaintiff and reasonable consumers suffered economic injury based on the
- If they had known the truth about Defendant's false and misleading Representations, Plaintiff and reasonable consumers would not have purchased the

B. Defendant Manufactures, Markets and Labels the Products

- Defendant Vi-Jon, Inc. manufactures, advertises and labels numerous hand sanitizing products sold under store brand names, including the following brands: (i) CVS Health and/or CVS pharmacy ("CVS"), (ii) equate (Walmart), (iii) germ-x, and (iv)
- Attached hereto as Exhibit 2 are images of the front and back panels of the
- On the front facing, principal display panel, Defendant states that the

⁴ The Products are sold in various sizes, scents and variations. This action includes in the definition of Products all sizes, scents and variations of the Products that bear the "kills 99.99% of germs", "kills more than 99.99% of germs" and "kills 99.99% of harmful germs" representation on the <u>principal</u> display panel.

⁵ Specifically, the CVS products state "kills 99.99% of germs" and "KILLS 99.99% OF HARMFUL GERMS"; the equate products state "KILLS 99.99% OF GERMS"; the germ-x products state "kills more than 99.99% of germs"; and the Walgreen products state "kills 99.99% of germs" and "kills more than 99.99% of germs".

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<#>The Products, however, do not "kill" 99.99% of the organisms that cause disease.

- <#> The Products are substantially ineffective against certain microbes, including certain non-enveloped viruses (for example, norovirus), protozoa (for example, the microbe that causes toxoplasmosis), and bacterial spores (for example, the organism that causes the gastric condition, C. difficile). ¶
 <#>The microbes, or "germs," for which the Products are ineffective
- comprise more than .01% of germs. Accordingly, the uniform, material Representation that the Products kill 99.99% of germs is false and misleading, and Defendant omits material information concerning the limitations of the Products in making the Representation.¶
 <#>The Products, for example, are generally ineffective at killing
- norovirus which, according to the Center for Disease Control ("CDC"), accounts for approximately 50% of all outbreaks of foodrelated illness in the United States.¶
 <#>According to the CDC, each year on average in the United
- States, norovirus causes 19 to 21 million cases of vomiting and diarrhea illness, entailing 2,270,000 outpatient clinic visits (mostly in young children), 465,000 emergency room visits (mostly in young children), 109,000 hospitalizations, and 900 deaths (mostly in adults 65 and older).
- <#>According to the CDC, hand washing with soap and water is more effective than hand sanitizer at removing certain kinds of germs, including norovirus. In fact, the CDC's norovirus expert acknowledged that norovirus is resistant to many common disinfectants. The CDC recommends using bleach to kill norovirus. <#>The reason for this limitation is straightforward—norovirus has a structure known as a capsid—a protein shell—which alcohol cannot readily penetrate. Because the

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Deleted: <object> Defendant makes the Representation on the front panel of the CVS Product by offsetting it from the surrounding text by including it in a "call out" or "stamp" that highlights the text in a contrasting background. 4 Defendant makes the Representation on the front panel of the equate Product by offsetting it from the surrounding text by including it in all caps inside of a 5 "call out" that highlights the text in a contrasting background. 6 7 51. Defendant makes the Representation on the front panel of the germ-x Product by including it in all red font. 8 9 Defendant makes the Representation on the front panel of the Walgreens product by including it as the final bullet point in a list of product attributes. The decisions made by Defendant regarding label appearance and set forth in paragraphs 48-52 were intentional. The decisions made by Defendant regarding label appearance and set forth 13 14 in paragraphs 48-52 make the Front Panel Representation prominent. Product manufacturers make prominent representations in order to increase 16 sales. 17 56. Defendant makes the prominent Front Panel Representation to increase sales of its Products. <u>18</u> 19 The Front Panel Representation is followed by an asterisk. 20 On the back panel of the Products, following an asterisk, Defendant states: "Effective at eliminating more than 99.99% of many common harmful germs & bacteria in as little as 15 seconds" or "Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds." <u>23</u> The language appears as follows on the Products: <u>24</u> • On the CVS Product, Defendant makes the Back Panel Statement at the <u>26</u> bottom of the Product label outside of the Drug Facts panel. In certain Deleted: FIRST Formatted: Font: 14 nt <u>27</u> of the CVS Products, Defendant includes the Back Panel Statement in Deleted: 28 very small font that is substantially smaller than the font on the Drug Formatted: Left Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

Deleted: <object> Facts panel. In some of the CVS Products, the statement is made on a peel-off panel. On the equate Product, Defendant makes the Back Panel Statement 4 below the Drug Facts panel. The Back Panel Statement appears in small black font on a blue or green background. On the germ-x Product, Defendant makes the Back Panel Statement 6 above the Drug Facts panel against a silver background. The Back Panel 8 Statement appears in very small font that is substantially smaller than 9 the font used for the Drug Facts panel. On the Walgreens Product, the Back Panel Statement is included in very small font that is substantially smaller than the font used for the Drug Facts panel. 13 • In addition, the Back Panel Statement on the Walgreens Product is 14 printed perpendicular to the Drug Facts, so a consumer must rotate the bottle in order to read it. The decisions made by Defendant regarding label appearance and set forth 16 17 in paragraphs 58-59 were intentional. Deleted: each of The decisions made by Defendant regarding label appearance and set forth 18 Deleted: , the Products are ineffective against norovirus. Formatted: Justified 19 in paragraphs 58-59 made the Back Panel Statement harder for a consumer to review. Deleted: <#>Norovirus alone renders the Representation that the especially during the purchase process. Products kill 99.99% of germs false and misleading. Yet, it is not 20 the only microbe for which the Products are ineffective <#>As described herein, the Products are also generally ineffective 21 C. The Products Have a Non-Monograph Status against numerous organisms that cause disease, including poliovirus, polyomavirus, hand foot and mouth disease virus, human papillomavirus ("HPV"), hepatitis A and cryptosporidium. 62. The active ingredient in the Products is ethyl alcohol. <#>Furthermore, each classification of virus or microbe has numerous different types or strains of "germs" that cause disease. For example, there are approximately 25 different strains of Low Compute, there are approximately 25 different strains of norovirus that affect humans, and more than 100 different types of HPV. \P The amount of ethyl alcohol in the Products ranges between 63% to 70%. <u>24</u> <#>The The U.S. Food and Drug Administration ("FDA") has deferred any Formatted: Justified rulemaking on whether the active ingredient in the Products, ethyl alcohol, is generally Deleted: <u>26</u> Deleted: FIRST recognized as safe or generally recognized as effective for use in consumer antiseptic Formatted: Font: 14 nt rubs because it determined that additional safety and effectiveness data is needed. See Deleted: Formatted: Left 28 21 CFR 310, FDA-2016-N-0124, at 14848 (April 12, 2019). Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

1 65. Accordingly, the Products have a nonmonograph status, meaning there is no generally accepted FDA language for labeling and marketing the Products. 7 66. Despite their nonmonograph FDA status, the Products are misbranded under identical federal and California laws. 67. The facts below demonstrate that the Products' labeling is false and/or misleading, rendering the Products misbranded. 68. As a result of this misbranding, it is unlawful for any person to manufacture, sell, deliver, hold, offer for sale, or receive the Products in commerce. See federal Food, Drug and Cosmetic Act §§ 331 et seq.; Cal. Health & Safety Code §§ 111440-111450. 69. To be clear, Plaintiff does not bring this action pursuant to any FDA	'ess.
no generally accepted FDA language for labeling and marketing the Products. 7 66. Despite their nonmonograph FDA status, the Products are misbranded under identical federal and California laws. 67. The facts below demonstrate that the Products' labeling is false and/or misleading, rendering the Products misbranded. 68. As a result of this misbranding, it is unlawful for any person to manufacture, sell, deliver, hold, offer for sale, or receive the Products in commerce. See federal Food, Drug and Cosmetic Act §§ 331 et seq.; Cal. Health & Safety Code §§ 111440-111450. 69. To be clear, Plaintiff does not bring this action pursuant to any FDA	less.
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5 67. The facts below demonstrate that the Products' labeling is false and/or misleading, rendering the Products misbranded. 68. As a result of this misbranding, it is unlawful for any person to manufacture, sell, deliver, hold, offer for sale, or receive the Products in commerce. See federal Food, Drug and Cosmetic Act §§ 331 et seq.; Cal. Health & Safety Code §§ 111440-111450. 69. To be clear, Plaintiff does not bring this action pursuant to any FDA	less.
misleading, rendering the Products misbranded. 8. As a result of this misbranding, it is unlawful for any person to manufacture, sell, deliver, hold, offer for sale, or receive the Products in commerce. See federal Food, Drug and Cosmetic Act §§ 331 et seq.; Cal. Health & Safety Code §§ 111440-111450. 69. To be clear, Plaintiff does not bring this action pursuant to any FDA	less.
68. As a result of this misbranding, it is unlawful for any person to manufacture, sell, deliver, hold, offer for sale, or receive the Products in commerce. See federal Food, Drug and Cosmetic Act §§ 331 et seq.; Cal. Health & Safety Code §§ 111440-111450. 69. To be clear, Plaintiff does not bring this action pursuant to any FDA	less.
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Drug and Cosmetic Act §§ 331 et seq.; Cal. Health & Safety Code §§ 111440-111450. 69. To be clear, Plaintiff does not bring this action pursuant to any FDA	less.
69. To be clear, Plaintiff does not bring this action pursuant to any FDA	
11 regulation, but under the applicable consumer protection laws and common law, which	
12 require that Defendant truthfully and accurately label the Products. Deleted: Specifically, Plaintiff brings this action Defendant's false and misleading representation the	
13 70. Specifically, Plaintiff brings this action based on Defendant's false and the Products to denature certain microbes that cause	e limitations of
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71. Resolution of Plaintiff's claims requires factual determinations as to	ges,
whether Defendant's Representations are false and whether they are misleading to	
reasonable consumers. Deleted: attorneys' fees and costs, and disgorger benefits Defendant has enjoyed from its unlawful s	
18 D. Reasonable Consumers Ascribe a Common Meaning to Certain Terms	
72. Certain words used on Defendant's Product labels have an ordinary or	
20 common meaning. Deleted: deceptive business practices, as detailed makes these allegations based on his personal known.	
21 73. "Germs" is a commonly understood term as a microorganism that causes otherwise,	itions and,
disease. https://www.merriam-webster.com/dictionary/germs.	
74. "Eliminate" means to put an end to or to get rid of. https://www.merriam-	
webster.com/dictionary/eliminate.	
25 75. "More than" is a quantifier meaning greater in size or amount or extent or Formatted: Justified	
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7 A monograph is described by the FDA as "a kind of 'recipe book' covering acceptable Deleted: →	
ingredients, doses, formulations, and labeling in over-the-counter drugs.	
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Deleted: <object> degree. https://www.definitions.net/definition/more+than. 76. "Common" means average or ordinary. https://www.definitions.net/ definition/common. 4 E. Consumers Trust that Defendant's Products are Truthfully Labeled 5 Consumers rely on Product labels for truth and accuracy. 6 Consumers are not required to turn a product over in order to read the "fine 7 print" on the back or side label and determine the truth of a statement on the front label. 8 A clarifying statement on the back or side label does not cure an affirmative 9 false statement or misrepresentation on the front label. Consumers are not charged with doing independent research or looking to other sources to determine the veracity of label statements. It is the responsibility of product manufacturers to truthfully label their 13 products. 14 The failure by a product manufacturer to disclose relevant information is, on its own, actionable. 16 F. Consumers Rely on Defendant's Products for Safety and Sanitization 17 Consumers, including Plaintiff, rely on Defendant's Products to disinfect 18 their hands and kill germs. 19 84. There was a rapid proliferation in hand sanitizer sales due to the COVID-<u>20</u> 19 pandemic. See https://www.nytimes.com/2020/03/11/smarter-living/wirecutter/ <u>21</u> coronavirus-hand-sanitizer.html attached as Exh. 3 ("Hand Sanitizer Shortage <u>22</u> Where it isn't sold out, enterprising sellers are charging outrageously inflated prices <u>23</u> simply because they can. If you don't have any hand sanitizer, you're not likely to get <u>24</u> some while the manufacturers create enough supply to meet the frenzied demand caused by panic over coronavirus."). <u> 26</u> Deleted: FIRST 85. According to market analysis, "[i]ncreasing awareness towards hand Formatted: Font: 14 nt hygiene is gaining prominence on account of being an important measure to restrict the Deleted: 28 Formatted: Left occurrence of nosocomial infections. Therefore, hand hygiene forms the most Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

as Exh. 4. 4 86. 6 7 8 87. 9 aggregate. 13 88. 14 16 17 18 19 **PARTIES** 24 <u>26</u>

important element of personal care, thereby driving the popularity of hand sanitizers." https://www.grandviewresearch.com/industry-analysis/hand-sanitizer-market, attached

Consumers, including Plaintiff, rely on Defendant's Representations for their truth: that the Products kill 99.99% of germs and eliminate 99.99% of many common harmful germs and bacteria.

JURISDICTION AND VENUE

- This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed class; (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims of the proposed class members exceed \$5,000,000 in the
- This Court has personal jurisdiction over Defendant because Defendant's contacts with the forum are continuous and substantial, and Defendant intentionally availed itself of the markets within California through the sale and distribution of the Products in California and through the privilege of conducting business in California.
- Venue is proper in this District pursuant to 28 U.S.C. §1391(b) because Defendant engages in continuous and systematic business activities within the State of California. Moreover, a substantial part of the events and omissions giving rise to the claims alleged herein occurred in this district. See also Declaration of Anthony Moreno In Support of Second Amended Complaint and Regarding Venue Pursuant to Cal. Civ. Code § 1780(d), attached as Exh. 5.

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- Plaintiff Anthony Moreno is a resident of San Diego, California who purchased each of the Products during the class period, as described herein. Plaintiff's claim is typical of all Class members in this regard.
- The advertising and labeling on the package of the Products purchased by Plaintiff, including the Representations, is typical of the advertising, labeling and

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Deleted: <object> Deleted: Representation <u>representation</u> of the Products purchased by members of the Class. Deleted: At the time of purchase, Plaintiff saw the Products labeling and Representation and understood it as a representation The price paid by Plaintiff for the Products is typical of the price by and warranty that the Products kill 99.99% of germs. Accordingly, the Representation and warranty were part of the basis of the bargain and Plaintiff would not have purchased the Products on the same 3 members of the Class. terms had he known that the Representation was not true 4 Plaintiff relied on Defendant's Representations, as described below. Deleted: Missouri corporation Plaintiff's reliance on Defendant's Representations is typical of the reliance Formatted: No underline Formatted: Heading 1, Left, Line spacing: single of the members of the Class. Widow/Orphan control, Tab stops: Not at 0.56" 6 Defendant Von-Jon, Inc. is a **Delaware Limited Liability Company** with its Moved (insertion) [1] **Deleted:** A.→<u>Defendant Manufactures, Labels and</u> 8 principal place of business in Saint Louis, Missouri. Advertises the Products Defendant manufactures, labels, advertises, and sells the 9 Defendant and its agents manufacture, market, distribute, label, promote, The following images depict the Products' primary display advertise and sell the Products. 97. At all times material hereto Defendant was conducting business in the <obiect> United States, including in California, through its services as a manufacturer and supplier to various stores in California and by, among other things, maintaining agents for the 13 14 customary transaction of business in California. Defendant and its agents promoted, marketed and sold the Products at issue in this jurisdiction and in this judicial district. The unfair, unlawful, deceptive, and misleading advertising and labeling of the Products was prepared and/or approved by Defendant and its agents, and was 18 <u>19</u> disseminated by Defendant and its agents through labeling and advertising containing the misrepresentations and omissions alleged herein. FACTUAL ALLEGATIONS . [1] A. Defendant's Front Panel Representation is False and Misleading Moved up [1]: Panel Representation that the Products kill 99.99% of germs is false and misleading. "Germs" is defined by Merriam-Webster as, among other 100. Defendant's Front Panel Representation that the Products kill 99.99% of Deleted: On information and belief, Defendant has not conducted efficacy studies, or scientifically valid and accurate <u>24</u> germs is false and misleading. studies, on all germs in order to substantiate its Representation Deleted: 101. "Germs" is defined by Merriam-Webster as, among other things. Deleted: " and <u>26</u> Deleted: FIRST "especially: a microorganism causing disease". Formatted: Font: 14 nt The Products do not "kill" certain germs, which comprise more than .01% Deleted: Formatted: Left of germs. Formatted: Font: 14 pt 12 SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

103. The Products do not "kill" certain germs, which comprise more than .01% of common germs.

104. <u>The Products do not "kill" certain germs, which comprise</u> more than .01% of harmful germs.

105. Defendant's Products are ineffective against numerous microbes, which are responsible for millions of cases of illness in the United States each year.

106. The active ingredient in the Products, ethyl alcohol, cannot <u>disrupt the structure of numerous types of viruses and pathogens and therefore cannot "kill" them.</u>

107. The Products are generally ineffective against, for example, commonly occurring non-enveloped viruses, protozoa pathogens, and certain bacterial spores.

108. Examples of the types of microbes against which the Products are ineffective include; norovirus, HPV, giardia, cryptosporidium, enterococcus, poliovirus and MRSA. https://bestlifeonline.com/hand-sanitizer-germs/, attached as Exh. 6.

109. In addition, the <u>Products have limited efficacy against certain common</u> bacterium, including pseudomonas aeruginosa, staphylococcus, and E. coli. *Id.*

110. Nonenveloped viruses, for example "are characterised [sic] by a higher resistance to chemical, physical procedures and other environmental influences and, if applicable, require the use of particularly powerful disinfectants that possess virucidal activity." See bode-science-center.com/center/glossary/nonenveloped-viruses.html, attached as Exh. 7.

111. The BODE SCIENCE CENTER, since 2011 "has dealt with current issues related to hygiene and infection prevention" and "has paved the way in the field of hand hygiene and has achieved key successes—for example with the responsible rub-in method for hygienic hand disinfection." https://www.bode-science-center.com/fileadmin/ user_upload/download-en/BSC_Imageflyer_E.pdf, attached as Exh. 8.

112. BODE/HARTMANN manufactures disinfection products for hands, skin, surface and instruments.

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Deleted: where hands are dirty, grimy or greasy. In addition, the effectiveness of ABHS is reduced based on the Products' use directions, which require only a single application on the hands "until dry." This short exposure time is insufficient to inactivate certain microbes, particularly because ethyl alcohol evaporates quickly.

The composition of certain

Deleted: render the Products substantially ineffective, particularly under the proscribed manner of use.

Deleted: Examples of certain types of diseases caused by each of these types of microbes are described below. These examples are included for illustrative purposes and to show that the Products are ineffective against more than 0.01% of "germs." These examples are not, however, a comprehensive summary of all microorganisms

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The Products are Ineffective Against Non-Enveloped Viruses
Non-enveloped viruses are composed of dense genetic material that
is tightly packed with proteins and difficult to disrupt. Examples of
non-enveloped viruses

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113. Unlike the Products at issue, which contain at most 70% ethyl alcohol, the Sterillium® med, Gel and Gel pure hand disinfection products offered by BODE/HARTMANN contain 85% ethanol.

114. The BODE SCIENCE CENTER compiled a database of pathogens, including a "disinfectant" spectrum of activity necessary to kill the respective microorganism." See https://www.bode-science-center.com/center/relevant-pathogensfrom-a-z.html, attached as Exh. 9 (the "Database").

- 115. The Database lists approximately 204 pathogens. *Id.*
- 116. Of the 204 listed pathogens, 16 are virucidal. Id.
- 117. The Products are ineffective or substantially ineffective against the 16 pathogens listed as virucidal. 8
 - 118. Of the 204 listed pathogens, 7 are listed as sporicidal. *Id.*
- 119. The Products are ineffective or substantially ineffective against the 7 pathogens listed as sporicidal.
- 120. Of the 204 listed pathogens, 31 are listed as "[s]pecific disinfectants effective against parasites are required." *Id.*9
- 121. The Products are ineffective or substantially ineffective against the 31 pathogens listed as "[s]pecific disinfectants effective against parasites are required."
- 122. Accordingly, in total, of the 204 listed pathogens, the Products are ineffective or substantially ineffective against 54 of the listed pathogens, or approximately 26% of all listed pathogens.
- 123. The Database, even if not a comprehensive summary, exemplifies the falsity of Defendant's Representations.

⁸ Ethanol at 85% is substantially effective against many pathogens listed as "Virucidal." By contrast, the Products at issue are ineffective or substantially ineffective against these pathogens because the Products contain at most 70% ethyl alcohol.

Some of the listed pathogenic parasites are uncommon in the United States or in humans.

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<#>The Products Are Ineffective Against Spores \$\) <#>C. difficile. C. difficile is a major spore forming bacteria, which causes between 15-55% of all diarrheas. C. difficile bacteria have complex layers of spore coats, which render ABHS ineffective. <#>According to the CDC, within a month of diagnosis, 1 in 11 people over the age of 65 died of a healthcare associated C. difficile infection.

<#>In addition, according to a publication from the National Center for Biotechnology Information from the U.S. National Library of Medicine, C. difficile is associated with high morbidity and the cost of C. difficile infections is estimated at \$5.4 billion in the United

<#>According to the CDC, washing with soap and water is the only way to prevent the spread of C. difficile from person to person

<#>Other Studies Showing the Products May be Ineffective
<#>Enterococci. Enterococcal bacteria are responsible for infections that affect the digestive tract, bladder, heart and other parts of the body and globally make up ten percent of all bacterial infections acquired in a hospital setting. There are at least 18 different species of enterococcal bacteria. In North American and Europe enterococci are a leading cause of sepsis, a fatal blood

<#>A 2018 study published by Science Translational Medicine found that, as hand sanitizer use increased in hospital settings, the number of enterococcal infections also increased. One explanation for the increase is that enterococci are becoming increasingly tolerant of alcohol-based hand sanitizers. Although, at the time of the study the bacteria were generally denatured by a 70% alcohol concentration, alcohol resistance is increasing over time. Bacteria collected after 2009, for example, were ten times more resistant to alcohol than pre-2004 bacteria. The study concludes that certain bacteria should be addressed with simple hand washing, rather than application of alcohol-based hand sanitizer.

#>Influenza A. Although controversial, a 2019 study from researchers at the Kvoto Profectural University of Medicine found that ethanol-based hand sanitizers would have to be in contact with the influenza A (flu) virus for at least four minutes before killing it. The reason ethanol-based disinfectants might not be as useful as previously thought has to do with the mucus that surrounds droplets of the influenza A virus. The mucus acts as a hydrogel and protects the virus from the ethanol, the investigators reported." Furthermore the researchers found that, unlike sanitizer, "[e]ven hand washing without soap is effective against influenza viruses. Of course, hand washing with soap is also effective, and further increases in disinfection effects are expected."

#> Evaluated alone or collectively

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Deleted: <object> B. Defendant's Back Panel Statement is False and Misleading 124. Defendant's Back Panel Statement that the Products are "[e]ffective at eliminating more than 99.99% of many common harmful germs & bacteria in as little as 15 seconds" or "[e]ffective at eliminating 99.99% of many common harmful germs and 4 bacteria in as little as 15 seconds" is false and misleading. 5 125. As stated above, the Products are ineffective against numerous pathogens, 6 some of which are "common harmful germs and bacteria." 7 126. The "common harmful germs and bacteria" against which the Products are 8 ineffective include, but are not limited to: norovirus, cryptosporidium, HPV, and C. 9 difficile. 127. In addition, the Products have limited efficacy against other "common harmful germs and bacteria," including but not limited to: staphylococcus and E. coli. 128. The classes of common harmful germs and bacteria against which the 13 Products are ineffective are comprised of hundreds of different types or strains of germs 14 and bacteria. 129. Although not a comprehensive list of "common harmful germs and 16 bacteria" against which the Products are ineffective, the "common germs" described 17 herein demonstrate the falsity of Defendant's Back Panel Statement. 18 19 1. Norovirus is the Most Common Cause of Food Illness in the U.S. <u>20</u> 130. The Products are ineffective against norovirus. 21 131. According to the CDC, norovirus is "the leading cause of outbreaks from <u>22</u> contaminated food in the United States. About 50% of all outbreaks of food-related <u>23</u> illness are caused by norovirus," See https://www.cdc.gov/norovirus/trends-<u>24</u> outbreaks/outbreaks.html (Common Settings of Norovirus Outbreaks), attached as Exh. 10. <u> 26</u> Deleted: FIRST 132. "Most of these outbreaks (at restaurants and catered events) occur in food Formatted: Font: 14 nt service settings like restaurants. Infected food workers are frequently the source of Deleted: 28 Formatted: Left outbreaks in food-service settings, often by touching ready-to-eat foods, such as raw Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

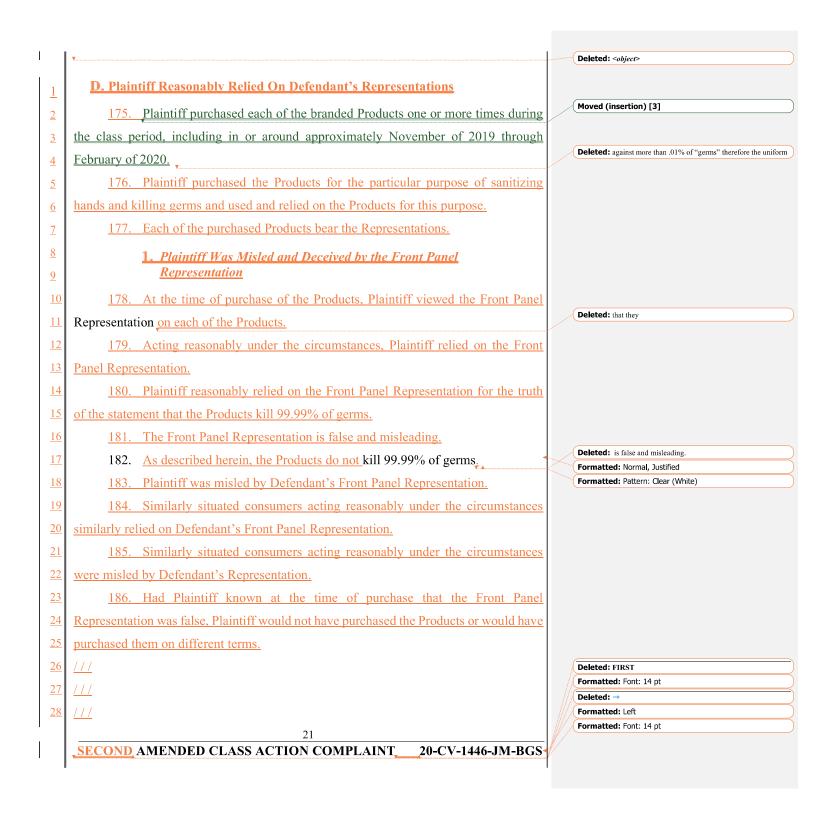
Deleted: <object> fruits and vegetables, with their bare hands before serving them." Id. 133. According to the CDC, norovirus "is the leading cause of vomiting and diarrhea from acute gastroenteritis (inflammation of the stomach and intestines) among 4 people of all ages in the United States. See https://www.cdc.gov/norovirus/trendsoutbreaks/burden-US.html (Burden of Norovirus Illness in the U.S.), attached as Exh. 5 6 <u>11.</u> 7 134. According to the CDC, each year, on average in the United States, norovirus 8 causes: 19 to 21 million cases of vomiting and diarrhea illness, entailing 2,270,000 9 outpatient clinic visits (mostly in young children), 465,000 emergency room visits (mostly in young children), 109,000 hospitalizations, and 900 deaths (mostly in adults 65 and older). *Id*. 135. Defendant's Products do not kill norovirus. 13 136. "Norovirus is enclosed by a structure known as a capsid. Alcohol cannot get through it, which is why alcohol-based hand sanitizers do not kill norovirus." 14 15 https://www.nbcnews.com/health/health-news/5-things-you-didn-t-know-about-nastystomach-flu-n714241, attached as Exh. 12. 16 17 Crytosporidium Is One of the Common Causes of Infectious Diarrhea 18 19 137. Defendant's Products are ineffective against cryptosporidium. 20 138. Cryptosporidium (or Crypto) "parasites are one of the more common causes of infectious diarrhea in humans." See https://www.mayoclinic.org/diseases-<u>22</u> conditions/cryptosporidium/symptoms-causes/syc-20351870 (Cryptosporidium <u>23</u> infection), attached as Exh. 13. <u>24</u> 139. "Crypto is the leading cause of disease outbreaks in the United States linked to water, specifically outbreaks linked to pools or water playgrounds." <u> 26</u> Deleted: FIRST https://www.infectioncontroltoday.com/view/outbreaks-diarrhea-caused-Formatted: Font: 14 nt cryptosporidium-increased-2009-through-2017, attached as Exh. 14. Deleted: 28 Formatted: Left 140. Crypto is transmitted by hands. See Exh. 13 (one of the ways crypto is Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

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1	transmitted is by "[t]ouching your hand to your mouth if your hand has been in contact	
2	with a contaminated surface, object, person or animal.").	
<u>3</u>	141. "Alcohol-based hand sanitizers do not work effectively on Crypto." See	
<u>4</u>	<u>Exh. 14.</u>	
<u>5</u>	3. HPV Causes Common Warts on the Hands of About 25% of All People in the United States	
<u>6</u>	142. Defendant's Products are ineffective against human papillomavirus	
<u>7</u>	("HPV").	
<u>8</u>	143. "There are more than 150 different types of HPV, each with its own favorite	
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<u>10</u>	skin surface to invade. Some cause the small, painless, rough-surfaced warts found on	
<u>11</u>	the fingers and face. Others cause the larger, more painful and flatter plantar warts that	
<u>12</u>	grow on the soles of the feet." health.harvard.edu/a_to_z/human-papilloma-virus-hpv-	
<u>13</u>	a-to-z, attached as Exh. 15.	
<u>14</u>	144. "Human papilloma viruses usually are spread by direct skin contact, such	
<u>15</u>	as shaking the hand of someone who has a wart on their finger " Id.	
<u>16</u>	145. HPV causes common warts, which most often affect the hands, face, skin	
<u>17</u>	or scalp. Id.	
<u>18</u>	146. HPV causes flat warts, which typically occur on the face, neck, chest,	
<u>19</u>	forearms, wrists or hands. <i>Id.</i>	
<u>20</u>	147. HPV causes plantar arts, which are painful overgrowths on the soles of the	
<u>21</u>	feet. Id.	
<u>22</u>	148. HPV also causes genital warts. <i>Id</i> .	
<u>23</u>	149. "Health experts estimate that common warts can be found on the hands of	
<u>24</u>	about one-fourth of all people in the United States, especially children." <i>Id.</i>	
<u>25</u>	150. "Warts are very contagious. The virus can be spread from person to person	
<u>26</u>	or from different parts of the body through Touching something contaminated with	Deleted: FIRST
<u>27</u>	the virus, such as towels, doorknobs and shower floors."	Formatted: Font: 14 pt
<u>28</u>	https://my.clevelandclinic.org/health/diseases/15045-warts, attached as Exh. 16.	Deleted: → Formatted: Left
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Deleted: <abiect> 151. In addition, "research has shown high levels of HPV DNA on fingers of patients with current genital infections." See https://www.sciencedaily.com/ releases/2014/02/140212132944.htm ("Popular disinfectants do not kill HPV"), attached 4 as Exh. 17. 152. Data shows that "[c]hemical disinfectants in hand sanitizer[s]...do nothing <u>5</u> for preventing the spread of human papillomavirus." *Id.* 6 7 4. C. difficile Causes About 500,000 Cases of Illness Per Year 8 153. Defendant's Products are ineffective against Clostridioides difficile. 9 154. "C. diff (also known as Clostridioides difficile or C. difficile) is a germ (bacterium) that causes severe diarrhea and colitis (an inflammation of the colon)." https://www.cdc.gov/cdiff/what-is.html (What is C. diff?), attached as Exh. 18. 155. "One in 11 people over age 65 diagnosed with a healthcare-associated C. 13 diff infection die within one month." Id. 14 156. "Each year in the United States, about a half million people get sick from 15 C. difficile, and in recent years, C. difficile infections have become more frequent, severe 16 and difficult to treat. Recurrent C. difficile infections also are on the rise." See 17 mayoclinic.org/diseases-conditions/c-difficile/symptoms-causes/syc-20351691 18 (C.difficile infection), attached as Exh. 19. 19 157. "Illness from C. difficile most commonly affects older adults in hospitals <u>20</u> or in long-term care facilities and typically occurs after use of antibiotic medications. 21 However, studies show increasing rates of C. difficile infection among people traditionally not considered to be at high risk, such as young and healthy individuals who <u>23</u> haven't used antibiotics and who haven't been in a health care facility." *Id.* <u>24</u> 158. According to the CDC, "If someone with C. diff (or caring for someone with C. diff) doesn't clean their hands with soap and water after using the bathroom, <u>26</u> Deleted: FIRST they can spread the germs to everything they touch." Formatted: Font: 14 nt <u>27</u> Deleted: https://www.cdc.gov/cdiff/prevent.html, attached as Exh. 20. 28 Formatted: Left Formatted: Font: 14 pt 18 SECOND AMENDED CLASS ACTION COMPLAINT___20-CV-1446-JM-BGS

Deleted: <object> 159. "[W]hen someone else touches the skin of [an infected person], or the surfaces that person touched, they can pick up the germs on their hands." *Id.* 160. "Washing with soap and water is the only way to prevent the spread [of C. 4 diff] from person to person." Id. C. Defendant's Back Panel Statement is False and Misleading: The Products <u>5</u> Do Not Kill Common Germs and Bacteria In As Little as 15 Seconds 6 Moved (insertion) [2] Formatted: Font: 12 pt 7 1. The Products Are Ineffective Where Hands are Dirty, Grimy or Formatted: Normal, Line spacing: single, No bullets or **Greasy** 8 numbering Formatted: No underline 9 161. The ineffectiveness of the Products against certain microbes, including "common harmful germs and bacteria" is compounded by the condition of the hands on which the microbes are found. 162. According to the CDC, "[h]and sanitizers may not be as effective when hands are visibly dirty or greasy" and "hands may become very greasy or soiled in 14 community settings, such as after people handle food, play sports, work in the garden, or go camping or fishing." https://www.cdc.gov/handwashing/show-me-the-sciencehand-sanitizer.html, attached as Exh. 21. 16 17 163. "When hands are heavily soiled or greasy, hand sanitizers may not work well." Id. <u>18</u> 164. Defendant's Representations are additionally false and misleading because 19 the "germs" killed are reduced where hands are dirty, grimy or greasy. 20 21 2. The Products Are Ineffective Based on the Manner of Use 165. The Products must be used in a specific way to be effective or to be effective <u>23</u> <u>against certain germs.</u> <u>24</u> 166. According to Penn Medicine and the CDC, the proper way to use hand sanitizer is by applying enough sanitizer to cover both sides of your hands and between <u>26</u> Deleted: FIRST your fingers and rubbing it in thoroughly. "Pay attention to the back of your hands, Formatted: Font: 14 nt Deleted: thumbs, and between your fingers. Like washing your hands at a sink, this process should 28 Formatted: Left Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

Deleted: <object> take about 20 seconds." https://www.pennmedicine.org/updates/blogs/health-andwellness/2020/august/how-to-use-hand-sanitizer, attached as Exh. 22. 167. The CDC echoes this guidance and also cautions "Do NOT rinse or wipe 4 off the hand sanitizer before it's dry; it may not work well against germs." See Exh. 1 (Hand Sanitizer Use Out and About). 5 168. The Products may be ineffective against microbes that would otherwise be 6 killed by ethyl alcohol based on the manner of use. 7 8 169. One example of a microbe that would otherwise be killed by ethyl alcohol 9 but has survived the application of alcohol-based hand sanitizer is rhinovirus, which is responsible for the common cold. 170. A study published in the Journal of Medical Virology tested the efficacy of hand sanitizer versus hand washing with soap and water against human rhinovirus. See Abstract: Single Treatment With Ethanol Hand Rub Is Ineffective Against Human 13 Rhinovirus—Hand Washing With Soap and Water Removes the Virus Efficiently, 14 attached as Exh. 23. 171. The study noted that "ethanol-containing hand rubs are used frequently as 16 a substitute for hand washing with water and soap. However, not all viruses are 17 inactivated by a short term rubbing with alcohol." Id. 18 172. The study found, however, that "[h]and washing with soap and water 19 appeared to be much more efficient for removing rhinovirus from skin than rubbing 20 hands with an ethanol-containing disinfectant." Id. 21 173. This study is just one example of the falsity of Defendant's Representations <u>23</u> due to the manner of use of the Products. 174. Accordingly, Defendant's Representations are additionally false and <u>24</u> misleading because the Products may be ineffective where the sanitizer does not coat the <u> 26</u> hands, does not remain on the hands for a sufficient period of time, or is rubbed off prior Deleted: FIRST Formatted: Font: 14 nt <u>27</u> to becoming dry. Deleted: 28 Formatted: Left Formatted: Font: 14 pt 20 SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS



Deleted: <object> 2. Plaintiff was Misled and Deceived by the Back Panel Statement 187. During one or more hand sanitizer purchases, Plaintiff viewed the Back Panel Statement. 188. Plaintiff does not specifically recall whether he viewed the Back Panel 4 Statement at the time of the purchase of the Products at issue, but he viewed the Back 5 Panel Statement prior to the purchase of the Products. 6 189. At the time Plaintiff viewed the Back Panel Statement and at the time of 7 purchase of the Products, the Back Panel Statement did not change Plaintiff's reasonable 8 belief that the Front Panel Representation was true. 9 190. Accordingly, the Back Panel Statement did not clarify or cure the Front Panel Representation. 191. In addition, acting reasonably under the circumstances, Plaintiff relied on 12 13 the Back Panel Statement for the truth of the statement that the Products are effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 14 seconds. 15 192. As described herein, the Back Panel Statement is false and misleading. 16 193. Plaintiff was misled by Defendant's Back Panel Statement. 17 194. Similarly situated consumers acting reasonably under the circumstances 18 similarly relied on Defendant's Back Panel Statement. 19 195. Similarly situated consumers acting reasonably under the circumstances 20 were misled by Defendant's Back Panel Statement. 21 196. Had Plaintiff known at the time of purchase that the Back Panel Statement was false, Plaintiff would not have purchased the Products or would have purchased <u>23</u> them on different terms. <u>24</u> E. Plaintiff Suffered Economic Injury By Purchasing the Products <u> 26</u> Deleted: FIRST 197. As set forth in Exhibit 5, to the best of his knowledge and recollection, Formatted: Font: 14 nt Plaintiff purchased the Products as follows: Deleted: 28 Formatted: Left Formatted: Font: 14 pt 22 SECOND AMENDED CLASS ACTION COMPLAINT____ 20-CV-1446-JM-BGS

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1	198. Plaintiff purchased the CVS Product from a CVS store located in San	Moved (insertion) [4]
<u>2</u>	Diego, California for approximately \$3.99.	(
<u>3</u>	199. Plaintiff purchased the equate Product from a Walmart store located in San	 Moved (insertion) [5]
<u>4</u>	Diego, California for approximately \$3.97.	
<u>5</u>	200. Plaintiff purchased the germ-x Product from a Walmart store located in San	 (Moved (insertion) [6]
<u>6</u>	Diego, California for approximately \$2.66.	
<u>7</u>	201. Plaintiff purchased the Walgreens product from a Walgreens store located	(Moved (insertion) [7]
<u>8</u>	in San Diego, California for approximately \$2.99.	Deleted: C.→
9	202. Plaintiff purchased each of the Products for personal and family use.	
<u>10</u>	203. As stated herein, Plaintiff relied on Defendant's Representations on the	
<u>11</u>	Product labels in purchasing the Products.	
<u>12</u>	204. Plaintiff suffered an injury in fact by purchasing the Products.	
<u>13</u>	205. Plaintiff suffered an economic injury based on the loss of the benefit of the	
<u>14</u>	bargain between what was represented by Defendant—Products that kill 99.99% of	
<u>15</u>	germs—and what was received—Products that do not kill 99.99% of germs.	
<u>16</u>	206. Plaintiff suffered an economic injury based on the loss of the benefit of the	
<u>17</u>	bargain between what was represented by Defendant—Products that eliminate 99.99%	
<u>18</u>	of many common harmful germs and bacteria in as little as 15 seconds—and what was	
<u>19</u>	received—Products that do not eliminate 99.99% of many common harmful germs and	
<u>20</u>	bacteria in as little as 15 seconds.	
<u>21</u>	207. Plaintiff suffered an economic injury based on the amount paid for the	
<u>22</u>	Products, which he would not otherwise have purchased, or which he would have paid	
<u>23</u>	less for, had he known about Defendant's misrepresentations and omissions.	
<u>24</u>	208. Plaintiff did not suffer a speculative or hypothetical injury, but suffered	
<u>25</u>	actual harm based on the purchase price of the Products.	
<u>26</u>	209. Plaintiff's injury is traceable to Defendant's conduct due to Defendant's	Deleted: FIRST
<u>27</u>	false and misleading Representations and omissions.	Formatted: Font: 14 pt Deleted: →
<u>28</u>	210. If Plaintiff had known the truth, he would not have purchased the Products	Formatted: Left
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or would have paid less for them.

F. The Products Are Misbranded And Worthless Under the Law

- 211. The Products are over-the-counter drugs.
- 212. The FDA has been considering rulemaking concerning the category of "Topical Antimicrobial Drug Products: Consumer Antiseptic" for more than 45 years, since at least 1974. *See* 39FR33103.
- 213. In April of 2019, the FDA issued a Final Rule wherein it deferred any regulatory action for consumer antiseptic rub products that contain three ingredients, including ethyl alcohol, which is the active ingredient in the Products at issue. <u>See 21</u> CFR 310, FDA-2016-N-0124, at 14848 (April 12, 2019).
- 214. The FDA deferred making a monograph or nonmonograph finding for these products, meaning that there is no FDA approved "recipe book" for formulating and labeling the Products.
- 215. The facts described herein, however, demonstrate that the Products are misbranded under the law.
- 216. Identical federal and California laws govern the labeling of food, drugs and cosmetics.
- 217. The requirements of the federal Food, Drug & Cosmetic Act ("FDCA") were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law ("Sherman Law"). *See* Cal. Health & Safety Code § 110045-110135.
- 218. A drug or device is misbranded "if its labeling is false or misleading in any particular." *See* 21 U.S.C. § 352; Cal. Health & Safety Code § 111330.
- <u>219.</u> Misbranding reaches not only false claims, but also those claims that may be technically true, but are still misleading.
- 220. If any label representation is misleading, the entire product is misbranded and no other label statement can cure a misleading statement.
- 221. "It is unlawful for any person to distribute in commerce any food, drug, device, or cosmetic, if its packaging or labeling does not conform to the provisions of

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this article or to regulations adopted pursuant to this article." *See* Cal. Health & Safety Code § 110385.

- 222. "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded." § 111440.
 - 223. "It is unlawful for any person to misbrand any drug or device." § 111445.
- 224. "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device." § 111450.
- 225. As described herein, <u>Defendant's</u> label <u>Representations are false and the</u> Products are therefore misbranded under the law.
- 226. In addition, Defendant concealed or omitted material facts concerning the Products.
- 227. <u>Defendant knew or should have known that reasonable consumers would</u> <u>consider whether</u> the Products <u>are capable of being legally sold, delivered, held or received in commerce material in deciding to purchase the Products.</u>
- 228. At the time of purchase, Plaintiff and reasonable consumers did not know, and had no reason to know, that Defendant's Products were misbranded under the law and not capable of being legally sold, delivered, held or received in commerce ("Legally Saleable").
- <u>229.</u> Plaintiff and reasonable consumers attach importance to whether goods such as the Products at issue are Legally Saleable.
- 230. Plaintiff and reasonable consumers would not have purchased the Products had they known they were not Legally Saleable.
- <u>231.</u> To be clear, Plaintiff brings this action pursuant to California consumer protection law and the common law, and does not assert any claim for violation of the FDCA or the Sherman Law.
- 232. The FDCA and Sherman Law, however, provide a predicate violation for California's consumer protection laws and the common law.

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Deleted: and demonstrate that Plaintiff and Class members are entitled to a refund of the purchase price of the Products.

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Moved up [3]: Plaintiff purchased each of the branded Products one or more times during the class period, including in or around approximately November of 2019 through February of 2020.

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Plaintiff and consumers purchased the Products to their detriment.

Deleted: See Exhibit A. As set forth in Exhibit A, to the best of his knowledge and recollection, Plaintiff purchased the Products as follows.

Moved up [4]: Plaintiff purchased the CVS Product from a CVS store located in San Diego, California for approximately \$3.99.

Moved up [5]: Plaintiff purchased the equate Product from a Walmart store located in San Diego, California for approximately \$3.97.

Moved up [6]: Plaintiff purchased the germ-x Product from a Walmart store located in San Diego, California for approximately \$2.66.

Moved up [7]: Plaintiff purchased the Walgreens product from a Walgreens store located in San Diego, California for approximately \$2.99.

Deleted: Each of the purchased Products bear the Representation as described herein and in Exhibit A. Plaintiff purchased the Products for personal and family use. The price paid by Plaintiff was representative of the price paid by similarly situated consumers who purchased the Products. In addition, the Representation on the Products purchased by Plaintiff was the same as the Representation purchased by members of the Class.

In purchasing the Products, Plaintiff relied on Defendant's Representation that the Products kill 99,99% of germs.

Defendant knew or should have known that reasonable consumers would consider the Representation material in deciding to purchase the Products. Accordingly, Defendant's Representation is false, misleading and reasonable long the Products, Plaintiff did not know, and had no reason to know, that the Representation was false, misleading and deceptive. Plaintiff would not have purchased the Products, or would have purchased them on different terms, if he had known the truth.

Plaintiff suffered an ascertainable loss between the Products as represented by Defendant and as received. \(\) ... [8]

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CLASS DEFINITION AND CLASS ALLEGATIONS

233. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of himself, on behalf of all others similarly situated, and as a member the Class defined as follows:

All citizens of California who, within four years prior to the filing of the initial Complaint, purchased Defendant's Products and who do not claim any personal injury from using the Products (the "Class").

- 234. Excluded from the Class are: (i) Defendant, its assigns, successors, and legal representatives; (ii) any entities in which Defendant has a controlling interest; (iii) federal, state, and/or local governments, including, but not limited to, their departments, agencies, divisions, bureaus, boards, sections, groups, counsels, and/or subdivisions; (iv) all persons presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and (v) any judicial officer presiding over this matter and their staff, and persons within the third degree of consanguinity to such judicial officer.
- 235. Plaintiff reserves the right to amend or otherwise alter the class definition presented to the Court at the appropriate time, or to propose or eliminate sub-classes, in response to facts learned through discovery, legal arguments advanced by Defendant, or otherwise.
- 236. This action is properly maintainable as a class action pursuant to Federal Rule of Civil Procedure 23 for the reasons set forth below.
- 237. <u>Numerosity</u>: Members of the Class are so numerous that joinder of all members is impracticable. Upon information and belief, the Class consists of hundreds of thousands of purchasers throughout the State of California. Accordingly, it would be impracticable to join all members of the Class before the Court.

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238. <u>Common Questions Predominate:</u> There are numerous and substantial questions of law or fact common to all members of the Class that predominate over any individual issues. Included within the common questions of law or fact are:

- Whether the Product <u>Representations</u> and omissions are, or any single representation or omission is, false, misleading and/or deceptive;
- Whether Defendant engaged in unlawful, unfair or deceptive business practices by advertising, <u>labeling</u> and selling the Products;
- Whether Defendant violated California Bus. & Prof. Code § 17200, et seq.; Cal. Bus. & Prof. Code § 17500, et seq.; and/or the Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.;
- Whether Defendant committed a breach of express warranty;
- Whether the Products are misbranded <u>under the law;</u>
- Whether Plaintiff and the Class have sustained damage as a result of Defendant's unlawful conduct;
- The proper measure of damages sustained by Plaintiff and the Class; and
- Whether Defendant was unjustly enriched by its unlawful practices.
- 239. <u>Typicality:</u> Plaintiff's claims are typical of the claims of the members of the Class he seeks to represent because Plaintiff, like the Class members, purchased Defendant's misbranded Products. Defendant's unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were experienced. Plaintiff and the Class sustained similar injuries arising out of Defendant's conduct. Plaintiff's and Class member's claims arise from the same practices and course of conduct and are based on the same legal theories.
- 240. <u>Adequacy</u>: Plaintiff is an adequate representative of the Class he seeks to represent because his interests do not conflict with the interests of the members of the Class Plaintiff seeks to represent. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel experienced and competent in the prosecution of complex class actions, including complex questions that arise in

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consumer protection litigation.

- 241. <u>Superiority and Substantial Benefit</u>: A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all members of the Class is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:
 - The claims presented in this case predominate over any questions of law or fact, if any exists at all, affecting any individual member of the Class;
 - Absent a Class, the members of the Class will continue to suffer damage and Defendant's unlawful conduct will continue without remedy while Defendant profits from and enjoys its ill-gotten gains;
 - c. Given the size of individual Class members' claims, few, if any, members could afford to or would seek legal redress individually for the wrongs Defendant committed against them, and absent members have no substantial interest in individually controlling the prosecution of individual actions;
 - d. When the liability of Defendant has been adjudicated, claims of all members of the Class can be administered efficiently and/or determined uniformly by the Court; and
 - e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and members of the Class can seek redress for the harm caused to them by Defendant.
- 242. Because Plaintiff seeks relief for all members of the Class, the prosecution of separate actions by individual members would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendant.

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- 243. The prerequisites to maintaining a class action pursuant to Fed. R. Civ. P. 23(b)(3) are met as questions of law or fact common to Class members predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.
- 244. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Unfair and Unlawful Business Acts and Practices (Business and Professions Code § 17200, et seq.) (for Plaintiff and the Class)

- 245. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this complaint, as though fully set forth herein.
- 246. Defendant's conduct constitutes an unfair business act and practice pursuant to California Business & Professions Code §§ 17200, *et seq*. (the "UCL"). The UCL provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising"
- 247. Plaintiff brings this claim seeking restitution of the amounts Defendant acquired through the unfair, unlawful, and fraudulent business practices described herein.
- 248. Defendant's knowing conduct, as alleged herein, constitutes an "unfair" and/or "fraudulent" business practice, as set forth in California Business & Professions Code §§ 17200-17208.
- 249. Defendant's conduct was and continues to be unfair and fraudulent because, directly or through its agents and employees, Defendant made uniform materially false Representations and omissions.

250. As described herein, Defendant made the false and misleading Front Panel

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2	251. As described herein, Defendant made the false and misleading Back Panel	Deleted:	Products kill 99.99% of germs.	
<u>3</u>	Statement.			
<u>4</u>	252. As described herein, Defendant made omissions of material fact concerning			
<u>5</u>	the limitations of the Products to kill certain germs.	Deleted:		
<u>6</u>	253. As described herein, Defendant made omissions of material fact	Deleted:		
<u>7</u>	concerning the fact that the Products are misbranded under the law.	Deleted:	and that the Products are not Legally Saleab	le.
<u>8</u>	254. Defendant was and is aware that the <u>Representations</u> and omissions it has	Deleted:	: representations	
9	made about the Products were and continue to be false and misleading.			
<u>10</u>	255. Defendant had an improper motive—to derive financial gain at the expense			
<u>11</u>	of accuracy or truthfulness—in its practices related to the labeling and advertising of the			
<u>12</u>	Products.			
<u>13</u>	256. There were reasonable alternatives available to Defendant to further			
<u>14</u>	Defendant's legitimate business interests, other than the conduct described herein.			
<u>15</u>	257. Defendant's misrepresentation of material facts, as set forth herein, also			
<u>16</u>	constitute an "unlawful" practice because they violate California Civil Code §§ 1572,			
<u>17</u>	1573, 1709, 1710, 1711, and 1770 and the laws and regulations cited herein, as well as			
<u>18</u>	the common law.			
<u>19</u>	258. Defendant's conduct in making the Representations and omissions	Deleted:	Representation)
<u>20</u>	described herein constitutes a knowing failure to adopt policies in accordance with			
<u>21</u>	and/or adherence to applicable laws, as set forth herein, all of which are binding upon			
<u>22</u>	and burdensome to its competitors.			
<u>23</u>	259. This conduct engenders an unfair competitive advantage for Defendant,			
<u>24</u>	thereby constituting an unfair business practice under California Business & Professions			
<u>25</u>	Code §§ 17200-17208.			
<u>26</u>	260. In addition, Defendant's misrepresentations and omissions constitute an	Deleted:	: FIRST	
<u>27</u>	"unlawful" practice because the Product labels are "false or misleading in any particular"	Formatte Deleted:	ed: Font: 14 pt	
<u>28</u>	and the Products are therefore misbranded under the law. See 21 U.S.C. § 352; Cal.	Formatte	ed: Left	
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Deleted: <object> Health and Safety Code § 111330. 261. Because the Products are misbranded, they are not Legally Saleable. See Deleted: Accordingly, the Products are legally worthless Cal. Health and Safety Code §§ 110385, 111440, 111450. 4 262. Plaintiff and members of the Class could not have reasonably avoided injury. Defendant's uniform, material misrepresentations and omissions regarding the Products were likely to deceive, and Defendant knew or should have known that its 6 misrepresentations and omissions were untrue and misleading. 7 Deleted: Representation 8 263. Plaintiff purchased the Products in reliance on the Representations made 9 by Defendant, including that the Products' labeling was accurate as alleged herein, and without knowledge of Defendant's misrepresentations and omissions. 264. Plaintiff and members of the Class have been directly and proximately injured by Defendant's conduct in ways including, but not limited to, the monies paid to 13 Defendant for the Products, interest lost on those monies, and consumers' unwitting 14 support of a business enterprise that promotes deception and undue greed to the detriment of consumers, such as Plaintiff and Class members. 265. As a result of the business acts and practices described above, Plaintiff and 16 17 members of the Class are entitled to such Orders and judgments that may be necessary to disgorge Defendant's ill-gotten gains and to restore to any person in interest any 18 19 money paid for the Products as a result of the wrongful conduct of Defendant. 266. Pursuant to Civil Code § 3287(a), Plaintiff and the Class are further entitled 20 to pre-judgment interest as a direct and proximate result of Defendant's unfair and fraudulent business conduct. The amount on which interest is to be calculated is a sum <u>23</u> certain and capable of calculation, and Plaintiff and the Class are entitled to interest in an amount according to proof. <u>24</u> 26 Deleted: FIRST Formatted: Font: 14 nt Deleted: 28 Formatted: Left Formatted: Font: 14 pt 31 SECOND AMENDED CLASS ACTION COMPLAINT___ 20-CV-1446-JM-BGS

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2	SECOND CAUSE OF ACTION	
<u>3</u>	Deceptive Advertising Practices (California Business & Professions Code §§ 17500, et seq.)	
4	(for Plaintiff and the Class)	
<u>5</u>	267. Plaintiff re-alleges and incorporates by reference the allegations contained	
<u>6</u>	in the preceding paragraphs of this complaint, as though fully set forth herein.	
<u>7</u>	268. California Business & Professions Code § 17500 prohibits "unfair,	
<u>8</u>	deceptive, untrue or misleading advertising"	
9	269. Defendant violated § 17500 when it represented, through its false and	
<u>10</u>	misleading representations and omissions, that the Products possess characteristics and	Deleted: possessed
<u>11</u>	value that they do not have.	Deleted: did Deleted: actually
<u>12</u>	270. As described herein, Defendant made the false and misleading Front Panel	
<u>13</u>	Representation.	Deleted: that
<u>14</u>	271. <u>As described herein, Defendant made</u> the <u>false and misleading Back Panel</u>	Deleted: Products kill 99.99% of germs
<u>15</u>	Statement.	
<u>16</u>	272. Defendant's deceptive practices were designed to induce reasonable	
<u>17</u>	consumers like Plaintiff to purchase the Products.	
<u>18</u>	273. Defendant's uniform, material misrepresentations and omissions regarding	
<u>19</u>	the Products were likely to deceive, and Defendant knew or should have known that its	
<u>20</u>	uniform misrepresentations and omissions were untrue and/or misleading.	
<u>21</u>	274. Plaintiff purchased the Products in reliance on the Representations made by	Deleted: Representation
<u>22</u>	Defendant, including that the Product labeling was accurate as alleged herein, and	
<u>23</u>	without knowledge of Defendant's misrepresentations and omissions.	
<u>24</u>	275. Plaintiff and members of the Class have been directly and proximately	
<u>25</u>	injured by Defendant's conduct in ways including, but not limited to, the monies paid to	Deleted: Subclass
<u>26</u>	Defendant for the Products, interest lost on those monies, and consumers' unwitting	Deleted: FIRST
<u>27</u>	support of a business enterprise that promotes deception and undue greed to the	Formatted: Font: 14 pt Deleted: →
<u>28</u>	detriment of consumers, such as Plaintiff and <u>Class</u> members.	Formatted: Left Formatted: Font: 14 pt
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	SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS-	V

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Deleted: <object> 286. Defendant violated Section 1770(a)(5) by representing that the Products have "characteristics, . . . uses [or] benefits . . . which [they] do not have" in that the 3 Products are falsely and misleadingly labeled and represented, as described herein. 4 287. Defendant violated section 1770(a)(7) by representing that the Products "are of a particular standard, quality, or grade . . . if they are of another" by making the Deleted: Representation that the Products kill 99.99% of germs false and misleading Representations described herein. 6 and by representing that the Products are legally saleable when they are not 288. In addition, Defendant violated section 1770(a)(9) by advertising the 7 Products "with intent not to sell them as advertised" in that the Products are 8 9 misrepresented and misbranded as described herein. 289. Defendant's uniform, material, misrepresentations and omissions regarding the Products were likely to deceive, and Defendant knew or should have known that its misrepresentations and omissions were untrue and misleading. 13 290. Plaintiff and members of the Class relied on Defendant's Representations 14 and could not have reasonably avoided injury. 291. Plaintiff and members of the Class were unaware of the existence of facts Deleted: and that Defendant suppressed and failed to disclose. 16 17 292. Plaintiff and members of the Class would not have purchased the Products and/or would have purchased them on different terms had they known the truth. 18 19 293. Plaintiff and members of the Class have been directly and proximately injured by Defendant's conduct. 20 294. Such injury includes, but is not limited to, the purchase price of the Products and/or the price of the Products at the prices at which they were offered. 295. Moreover, Defendant's conduct is malicious, fraudulent, and/or wanton in that Defendant intentionally misled and withheld material information from consumers, <u>24</u> including to increase the sale of the Products. <u> 26</u> 296. Pursuant to California Civil Code § 1782(a), on February 10, 2020 and Deleted: FIRST Formatted: Font: 14 nt March 11, 2020, Plaintiff on his own behalf, and on behalf of members of the Class, Deleted: 28 provided notice to Defendant of the alleged violations of the Consumer Legal Remedies Formatted: Left Formatted: Font: 14 pt SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

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germs.

303. Defendant created express warranties that the Products are effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 15 seconds.

- 304. The express warranties appear on all labels of the Products and specifically relate to the goods being sold.
- 305. Despite Defendant's express warranties about the nature of the Products, the Products do not comport with the <u>Representations</u>. Thus, the Products were and are not what Defendant represented them to be.
- 306. Accordingly, Defendant breached the express warranties about the Products and their qualities because the Products do not conform to Defendant's affirmations and promises.
- 307. Plaintiff provided Defendant with pre-suit notice of the breach of warranty, including by letters dated February 10, 2020 and March 11, 2020.
 - 308. Plaintiff and members of the Class purchased the Products.
- 309. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff and members of the Class were harmed in the amount of the purchase price they paid for the Products.
- 310. Further, Plaintiff and members of the Class have suffered and continue to suffer economic losses and other general and specific damages including, but not limited to, the amounts paid for the Products, and any interest that would have accrued on those monies, in an amount to be proven at trial.

FIFTH CAUSE OF ACTION QUASI-CONTRACT

(for Plaintiff and the Class)

311. Plaintiff repeats and re-alleges the allegations of the preceding paragraphs as if fully set forth herein.

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SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS

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(for Plaintiff and the Class)

Plaintiff repeats and re-alleges the allegations of the preceding paragraphs as if fully set forth herein.

There was an implied warranty of merchantability that accompanied each retail sale of the Products and Defendant did not specifically disclaim such warranty.

As described herein, Defendant impliedly warranted that the Products kill 99.99% of germs and that they are Legally Saleable. ¶Defendant breached the warranty implied in the contract for the sale of the Products because the Products: (i) cannot pass without objection in the trade under the contract description; (ii) were not of fair average quality within the Product description; (iii) were not adequately labeled; (iv) were unfit for their intended and ordinary purpose; and (v) did not conform to the Representation on the Product label that they kill 99.99% of germs. As a result, Plaintiff and Class members did not receive the goods as impliedly warranted by Defendant to be merchantable. ¶

Plaintiff and Class members purchased the Products in reliance on Defendant's skill and judgment and the implied warranties. ¶
The Products were not altered by Plaintiff or Class members. ¶
Plaintiff gave Defendant notice within a reasonable time after Plaintiff knew or should have known that the Products were not fit for their intended purpose and/or not otherwise merchantable. ¶
As a direct and proximate cause of Defendant's breach of implied warranty, Plaintiff and members of the Class were harmed in the amount of the purchase price they paid for the Products. Further, Plaintiff and members of the Class have suffered and continue to suffer economic losses and other general and specific damages including, but not limited to, the amounts paid for the Products, and any interest that would have accrued on those monies, in an amount to be proven at trial. ¶

SIXTH CAUSE OF ACTION

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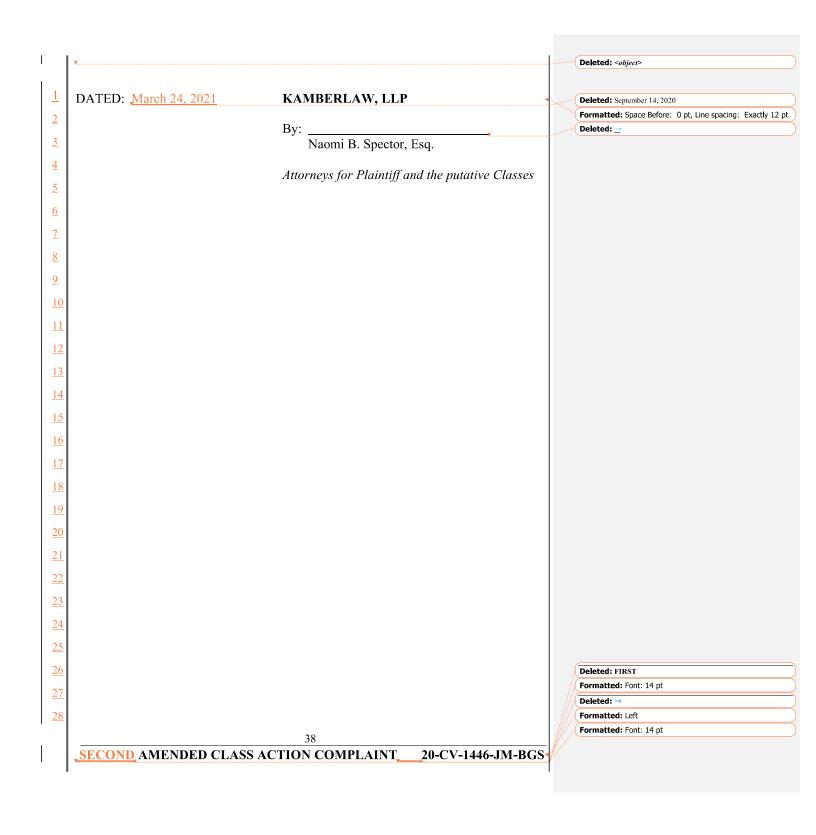
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Deleted: <object> 312. By purchasing the Products, Plaintiff and members of the Class conferred a benefit on Defendant in the form of the purchase price of the Products. 313. Defendant had knowledge of such benefits. 4 314. Defendant appreciated the benefit because, were consumers not to purchase the Products, Defendant would not generate revenue from the sales of the Products. 315. Defendant's acceptance and retention of the benefit is inequitable and 6 unjust because the benefit was obtained by Defendant's fraudulent and misleading 7 **Deleted:** representations Representations and omissions and unlawful conduct. 8 9 316. Equity cannot in good conscience permit Defendant to be economically enriched for such actions at the expense of Plaintiff and members of the Class, and therefore restitution and/or disgorgement of such economic enrichment is required. Deleted: **PRAYER** Formatted: Widow/Orphan control WHEREFORE, Plaintiff, individually and on behalf of all others similarly 14 situated, prays for judgment against Defendant as follows: A. For an order certifying the Class under Rule 23 of the Federal Rules of Civil Procedure; naming Plaintiff as representative of the Class; and naming Plaintiff's 16 attorneys as Class Counsel to represent the Class; For an order declaring that Defendant's conduct violates the statutes and 18 19 laws referenced herein; For an order awarding, as appropriate, compensatory and monetary 20 C. damages, and restitution or disgorgement to Plaintiff and the Class for all causes of action; <u>23</u> D. For an order awarding attorneys' fees and costs; <u>24</u> E. For an order awarding punitive damages; F. For an order awarding pre-and post-judgment interest; and <u>26</u> G. For such other and further relief as the Court deems just and proper. Deleted: FIRST Formatted: Font: 14 pt <u>27</u> Deleted: 28 Formatted: Left Formatted: Font: 14 pt 37 SECOND AMENDED CLASS ACTION COMPLAINT 20-CV-1446-JM-BGS



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EXHIBIT 5

1 2 3 4	STINSON LLP John Moticka, MOSB 31760 (admitted pro hac vice) john.moticka@stinson.com 7700 Forsyth Blvd, Suite 1100, St. Louis, MO 63105 Telephone: 314.259.4562 Facsimile: 314.259.4467					
5	Megan McCurdy, MOSB 60071(admitted pro hac vice)					
6 7	megan.mccurdy@stinson.com 1201 Walnut, Suite 2900 Kansas City, MO 64106 Telephone: 816.691.2649 Facsimile: 816. 412.9733					
8						
9	Ashley Crisafulli, MOSB, 71852 (admitted pro hac vice) ashley.crisafulli@stinson.com					
10	1201 Walnut, Suite 2900 Kansas City, Missouri 64106 Talanhone: 816 601 2676 Faccimile: 816 412 0733					
12	Telephone: 816.691.2676 Facsimile: 816.412.9733					
13	SELTZER CAPLAN MCMAHON VITEK Daniel Eaton, CASB 144663					
14	eaton@scmv.com 750 B Street, Suite 2100					
15	San Diego, CA 92101 Telephone: 619.685.3052 Facsimile: 619.702.6880					
16	Attorneys for Defendant EDGEWELL PERSONAL CARE COMPANY, EDGEWELL PERSONAL CARE BRANDS, LLC, and EDGEWELL PERSONAL CARE, LLC UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA					
17						
18 19						
20	LAUREN SOUTER, individually, and	Case No. 20CV1486 TWR- BLM				
21	on behalf of others similarly situated,)				
22	Plaintiff,	DECLARATION OF BARBARA				
23	VS.	MASSA IN SUPPORT OF DEFENDANTS' MOTION TO				
24	EDGEWELL PERSONAL CARE COMPANY, EDGEWELL	DISMISS SAC				
25	PERSONAL CARE BRANDS, LLC,	[Notice of Motion and Motion; and				
26	and EDGEWELL PERSONAL CARE, SLLC,	Memorandum of Points and Authorities concurrently filed herewith]				
2728	Defendants.	Hearing Date: Hearing Time Court:				
	_ 1 .	Case No. 20CV1486 TWR-BL-M				

DECLARATION OF BARBARA MASSA

COMES NOW Barbara Massa and, under penalty of perjury, hereby declares as true and correct, the following:

- 1. I am more than eighteen years of age and am competent to give the testimony stated herein.
 - 2. I am the Global Program Manager at Edgewell Personal Care Brands, LLC.
- 3. I have personal knowledge regarding the matters stated herein, and if called upon as a witness, I could and would testify to them based on my personal knowledge.
- 4. I reviewed Paragraph 24 of Plaintiff's Second Amended Class Action Complaint in the above captioned case that contains a photograph of only a portion of the label on a canister of Wet Ones® Antibacterial Hand Wipes Tropical Splash.
- 6. Attached to this declaration as Exhibit A is a true and correct copy of the full front and back labels on a canister of a Wet Ones® Antibacterial Hand Wipes Tropical Splash as identified in Paragraph 24 of the Complaint.
- 7. The back label on Wet Ones® Antibacterial Hand Wipes contains the following statements:
 - a. "Use decreases bacteria on skin."
 - b. "For external use only"
 - c. "Do not use if you are allergic to any of the ingredients."
- d. "When using this product do not get into eyes. If contact occurs, rinse thoroughly with water."
- e. "**Stop use and ask a doctor** if irritation or rash develops and continues for more than 72 hours."
- f. "**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away."
- g. "**Directions** adults and children 2 years and over apply to hands –allow hands to dry without wiping" and "children under 2 years ask a doctor before use."

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Case No. 20CV1486 TWR- BLM

1	h. "Wet Ones® Antibacterial Hand Wipes kill 99.99% of germs and wipe				
2	away dirt, providing a better clean than hand sanitizers."				
3	i. "They are specially formulated to be tough on dirt and germs, yet gentle on				
4	skin, so you can confidently keep your hands fresh and clean when soap and water are				
5	not available."				
6	8. I executed this declaration on the date set forth below in Naples, Florida.				
7	I DECLARE (OR CERTIFY, VERIFY, OR STATE) UNDER PENALTY OF				
8	PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.				
9					
10	Executed on April 8, 2022. By: Barbara Massa				
11	Barbara Massa				
12	Global Program Manager				
13	Edgewell Personal Care Brands, LLC				
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-	- 3 - Case No. 20CV1486 TWR- BLM				

EXHIBIT A



years and over ults and children

apply to hands
 allow skin to dry without wiping



Pediatrician Tested

Wet Ones® Antibacterial Hand Wipes kill 99.99% of germs and wipe away dirt, providing a better clean than hand sanitzers. They are specially formulated to be tough on dirt and germs, yet gentle on skin, so you can confidently keep your hands fresh and clean when soap and water are not available. Wet Ones® Canisters are great for at home use or on the-go and are designed to fit in most car cup holders for a fresh stan anywhere.

do not push finger through opening. TO DISPENSE WIPE: To avoid injury a waste basket after use. TO DISPOSE WIPE: Place in

DO NOT FLUSH





based on Nielsen scan data for 52 weeks ending 1/5/19. © 2019 Edgewell.

MADE IN THE

Net Ones is a trademark of EDGEWELL.

Wipe Dimensions: 5.7 in. x7.5 in. (14.6 cm x 19.) cm)
www. WetOnes. com
Dist. By ED GEWELL PERSONAL CARE BRANDS, LLC.
Sheiton CT 06484

Questions or Comments? Call 1-866-WET-111S; (1-866-938-1117), M-F

nactive Ingredients water, Alcohol Denat, Tenoxyethanol, PEG-8 Dimethicone, Caprylyl Hyposi, Dihydroxypropyl PEG-5 Linoleamhonium Thoride, Potassium Sorbate, Discolium (DTA, itric Acid, Fragrance, Aloe Barbadensis Leaf Julice.



